



ASSESSING LEGAL RESPONSES TO COVID-19

August 2020

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Summary of Findings and Recommendations

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Introduction

COVID-19 is the new virus this country has been preparing to take on for decades – and has, so far, failed miserably to stop. While peer countries have managed to get it under control, the United States faces rising cases and deaths. This is not a failure of resources: although decades of cutting health agency budgets is a big part of our problem, we remain a country rich in money and expertise. This is not a failure of individual courage; from health care workers through transport workers to people who produce and deliver food supplies, essential workers have shown up and done their jobs at significant personal risk. This has been, first and foremost, a failure of leadership and the implementation of an effective response.

This collection of 36 expert assessments shows that the COVID-19 failure is, in important ways, also a legal failure:

- Decades of pandemic preparation focused too much on plans and laws on paper, and ignored the devastating effects of budget cuts and political interference on the operational readiness of our local, state and national health agencies
- Legal responses have failed to prevent racial and economic disparities in the pandemic's toll, and in some cases has aggravated them – COVID-19 has highlighted too many empty promises of equal justice under law
- Ample legal authority has not been properly used in practice – we've had a massive failure of executive leadership and implementation at the top and in many states and cities.

The more important finding of this Report is that better use of legal tools can help turn things around right now. This Report offers more than 100 specific legal recommendations for the president and Congress, governors and state legislatures, and mayors and city councilors across the country. These recommendations encompass nearly all aspects of the response, and are organized into six priority areas: *Using Government Powers to Control the Pandemic*; *Fulfilling Governmental Responsibilities in a Federal System*; *Financing and Delivering Health Care*; *Assuring Access to Medicines and Medical Supplies*; *Protecting Workers and Families*; and *Taking on Disparities and Protecting Equal Rights*.

The findings and recommendations are those of each individual author, and they are sweeping. Experts in this Report call for fundamental structure changes to reduce the pernicious influence of politics on scientific decision making – like establishing the

U.S. Centers for Disease Control and Prevention (CDC) as an independent agency along the lines of the Federal Reserve. They suggest increasing the resilience of state economies by getting rid of rules that require states to balance their budgets even in crisis years. They recommend aggressive expansion of health care access through Medicaid and the Affordable Care Act, along with the removal of crucial barriers to care, like current immigration law and enforcement. They criticize multiple government failures in securing basic medical supplies and tests, and recommend a comprehensive reboot of federal coordination and procurement led by career government staff and free of petty political interference. They recognize the health risks and economic stress experienced by workers and families, and call for both continued economic-support legislation and better enforcement of occupational safety and health rules. Every author has found ways in which COVID-19 law has failed to address racial and economic disparities or made them worse. Authors find that states and cities have moved schooling online without removing legal barriers to – let alone ensuring – universal access to broadband internet; they have depended on low-wage workers in many sectors to keep the economy and vital services working, but have taken too little action to assure safe workplaces, provide paid sick leave, or recognize higher risk with higher pay; they have issued plans for allocating scarce medical services that violate laws protecting people with disabilities.

Each thematic section of the Report begins with a detailed list of recommendations, followed by the chapters laying out the underlying assessment and rationale. These chapters ask:

- Was the law (including both the law that existed prior to the pandemic and laws that took effect during the pandemic) a barrier or facilitator of the response in this topic area?
- What appear to be the major legal, structural, and implementation factors in effectiveness or ineffectiveness of legal and policy developments?
- Did the law or policy exacerbate racial, or socioeconomic or other pre-existing disparities?
- Was the law applied in a manner consistent with ethical values and constitutional norms?

This Summary, written by the editors, pulls out key high-level themes and aims to capture the broad thrust of the recommendations.

EQUITY AS A PRIMARY CONCERN OF THIS ASSESSMENT

Law and policy play an important role in limiting or exacerbating health disparities and health inequities. Health disparities are differences in health outcomes that people of different demographic backgrounds experience. Health disparities were all too common in the United States before COVID-19, and have been striking during the pandemic. As Patricia Williams points out in her powerful closing reflections on this Report, these disparities do not arise from bad individual choices or biological differences between races but the social factors that shape people's lives every day "in the ghettoized geographies that have become such petri dishes of contagion." These disparities are not inevitable. We as a society have created them. Centuries of oppression through policies, norms, and institutional practices shape individual experience and over time have created the inequitable society we inhabit.

Laws and policies too often reinforce health inequities by making resources scarce for many or creating unhealthy environments, especially in poor communities and communities of color. But the tools of law and policy can also be the deliberate intervention to change the fundamental drivers of inequity and increase health equity. We and our authors saw inequities all over the pandemic legal response, but also the moral and practical demand – we might even say craving – for cooperation, mutual aid, and solidarity. As Professor Williams concludes, "We can divide ourselves up into races and castes and neighborhoods and nations all we like, but to the virus—if not, alas, to us—we are one glorious, shimmering, and singular species."

Using Government Powers to Control the Pandemic

The COVID-19 pandemic in the United States is an unprecedented public health event that has demanded a multi-level response touching all levels of our society. Federal, state, local, and Tribal governments possess significant legal authority to intervene and respond to COVID-19, but, far too often, they have been slow and ineffective in their use of authority in the crisis.

Federal government leadership, coordination and even unprecedented levels of Congressional spending have been insufficient to meet the national need. Most of the recommendations aimed at the executive branch boil down to pleas for less political interference and more competent coordination and regulatory enforcement. It is not too late for the Trump administration to change course. At the very least, the CDC should be instructed (and allowed) to take the lead, and work with other relevant federal agencies, in developing rigorous, scientifically-grounded, and apolitical guidance for safe interactions between individuals and safe operation of schools, businesses, indoor spaces, and other settings to assist both government and private actors in assessing risk from COVID-19.

Congress needs to do more to fund state and local control efforts and to keep families and businesses above water through the worst economic downturn since the Great Depression. This legislative support should include legal protections against eviction, mortgage foreclosure, utility shutoff, discrimination, and employment loss, as well as funding for income support and unemployment benefits. Congress should also fund state, local, and Tribal efforts to implement supports, accommodations, and legal protections that enable individuals, families, employers, landlords, and communities to comply with social and physical distancing. Additionally, it is vital that Congress provide funding support for operations of state, local, and Tribal governments, many of which are constrained by balanced budget rules.

With the executive failure in mind, Congress should get started with a number of longer term structural reforms. Congress

should urgently consider reorganizing CDC and the Food and Drug Administration (FDA) as independent agencies along the lines of the Federal Reserve, enhancing their capacity and rendering them less susceptible to political influence. Congress should also amend the Public Health Services Act to add transparency and accountability mechanisms that require the U.S. Health and Human Services Secretary and CDC Director to provide scientific support for guidance and orders responding to the pandemic. In the face of executive failure or deliberate suppression of information, it is urgent for Congress to mandate and fund efforts to assure the collection and dissemination of accurate data. Disease surveillance reports should require enhanced demographic data collection that includes sexual orientation, gender identity, and disability status. To clear the way for better use of modern information technology in disease control, Congress should enact legislation that safeguards individuals from privacy and discrimination risks that arise from digital contact tracing and surveillance.

The state response has been hampered in some places by inter-branch and state-local fights over authority. State legislators, where necessary, should clarify the scope and authority of state executive officials to implement disease surveillance and data collection, testing and contact tracing, and physical distancing measures. State health departments should deploy these measures to protect the public's health and include transparent supporting scientific information with emergency orders implementing these measures. State legislatures should fund expansion of testing and tracing capacity and engage community-based organizations to facilitate connections with diverse local communities through multilingual and culturally-sensitive outreach efforts that will boost public trust. State legislation or executive orders also should provide incentives, funding, programmatic support, and legal protections to assist people with employment, housing, food access, physical and mental health care, social services, and income support, which will allow people to comply with public health guidance as well as mitigating economic and social harm. State health departments should collect detailed demographic

data to enhance targeted COVID-19 response efforts and should provide privacy and antidiscrimination protection for data collected through surveillance or digital contact tracing.

Fulfilling Governmental Responsibilities in a Federal System

Dividing authority among federal, state, local and Tribal governments – and between executives, legislatures and courts – is a strength of American governance – and a weakness. There is great potential in the system for creativity and responsiveness to local needs and values – but also high risk of confusion, infighting, and the breakdown of essential coordination. Leadership and the explicit delineation of roles and responsibility makes the difference in a crisis. For the last century at least, the federal government has provided broad expertise, clear guidelines and essential resources to state, Tribal and local governments, which have served as the front-line responders. The president has accepted responsibility for assuring that federal agencies respond effectively, and of amplifying and modeling compliance with federal advice.

Given the manifest failure of the Trump administration, many of the recommendations call for changes in the organization and operation of the federal government. In particular, because most states have constitutional limitations on deficit spending, only the federal government can supply the resources needed to ensure adequate testing and personal protective equipment (PPE), and research in and distribution of countermeasures. Likewise, only the federal government can soften the pandemic's economic impact and prevent it from exacerbating pre-existing inequities. The federal government needs to take more steps in each of these areas.

It is also critical that federal guidance and legal interventions be grounded, to the extent possible, on the best available scientific information. These add to the reasons for Congress to consider reorganizing the FDA and CDC as independent agencies, insulated from political interference, and for CDC to abstain from using its quarantine powers to achieve non-health related goals like immigration control. The federal government should also support essential policy experimentation by minimizing preemption of reasonable state and local control measures.

To help ensure that we are better prepared for the next pandemic, Congress and the president should jointly convene an independent commission of inquiry to investigate pandemic preparedness and the nation's response to COVID-19. Congress should also pass a joint resolution to reverse the president's decision to withdraw the U.S. from the World Health Organization, and Congress should continue funding that organization. Congress must also honor the federal government's trust responsibility and provide funding directly to American Indian and Native Alaskan Tribes, while sufficiently funding the Indian Health Service and Urban Indian Health Centers, as well as other Indian health programs.

There are also recommendations for state and local governments. States' response must also be guided, to the extent possible, by science. State orders should provide clarity as to the scientific basis that underlies them. State orders should also incorporate equity considerations. In addition, states should not preempt local laws that

RAPID ASSESSMENT EDITIONS

This is the first of two Reports we plan to release this year. This one has been assembled in just two months, with limited external review and a focus on immediate needs and recommendations. Over the next several months, we will be seeking broader input from a range of stakeholders, with the aim of producing a final report to inform the long-term policy agenda in 2021 and beyond. Readers with suggestions about any of the topics covered in this Report are invited to contact the authors or editors directly.

provide greater protection against the pandemic, or that enhance economic security or civil rights. States should also strengthen home rule; and local governments should advocate for state legislation or ballot initiatives that do so. States should also enact laws that require them to consult with Tribes within their boundaries, and work with Tribal governments to enter into data sharing and mutual aid agreements, while respecting Tribal authority and jurisdiction to promote the health welfare of their communities.

Financing and Delivering Health Care

The U.S. healthcare continues to critically underperform across multiple primary dimensions including access, financing, delivery, and the integration of technology. COVID-19 both emphasized these existing failings and highlighted some second level problems. The pandemic and its impact on employment demonstrated the over-reliance of health care access and financing on the employer-provided model; as millions of jobs were lost the ranks of the uninsured swelled. However, alternate public or private financing systems were unable to cope. Those without health insurance before COVID-19 suffered even more. The health of the disadvantaged, whether because of poverty, race, substance use, or congregate living declined still further as the virus further exposed the inadequacy of the country's safety-net. Many with health insurance suffered as much as the uninsured. Not all policies covered the tests and treatments necessary to combat COVID-19, often they were out-of-network and precipitated excessive "surprise bills." Additionally, the need for additional tests and treatments once again illustrated the out-of-pocket costs borne by an increasingly underinsured population.

This Report emphasizes some essential recommendations for the federal government. Medicaid is the key to many of the COVID-19 healthcare problems. As a result, Congress and the administration should step up with an enhanced Medicaid match during COVID-19 and its economic turmoil and also provide additional incentives to hold-out states to finally expand Medicaid. For those who remain or wish to remain in private health insurance markets, we recommend that Congress should authorize COBRA subsidies to help workers and their families to maintain comprehensive coverage. Similarly, both the federal and state governments should ease access to their individual markets with Special Enrollment Periods and extended end-dates. Federal legislation is urgently required to address deficiencies in health care coverages or their costs relating to COVID-19 testing and treatment, including cost-sharing, balance-

billing, and other impediments to care delivery. The federal government should increase its support for health care safety net providers by better targeting federal emergency provider grants, giving states greater Medicaid flexibility to help safety net providers, and helping uninsured patients gain access to the Provider Uninsured Claims Fund. The federal government should recognize that increased regulation and improved enforcement is necessary to protect nursing home residents and staff, yet there is no justification for exceptional rules that, for example, deny women their reproductive health during the pandemic or those in the LGBT communities access to HIV medication and gender confirmation services.

State governments should be aggressive in pursuing Medicaid waivers and other avenues to streamline application and enrollment processes and to increase eligibility and services. States should prioritize assistance to State safety net providers, expand their funding of telehealth programs, and use their own budgets to extend coverage to non-citizens. With regard to their regulation of private insurance, the states should be conscious of the existential attack on the Affordable Care Act currently before the Supreme Court, and make overdue changes to the affordability of their insurance markets by introducing a “public option” and stabilizing their insurance risk pools.

Local governments are, for the most part, observers in the health care funding debate, but they can do important things to make healthcare more accessible. For example, they can remove barriers to effective care for Substance Use Disorder by modifying zoning and licensing laws that create barriers to the establishment of and access to methadone treatment facilities.

Assuring Access to Medicines and Medical Supplies

The United States was unprepared for the surge in demand for basic medical equipment for testing, infection control and care. From the outset, there was a shortage of personal protective equipment like masks and gowns, and fears that ventilators would be next. Soon after there were shortages in swabs, reagents, pipettes and other supplies for testing. Between long-term cuts in federal staffing, poor leadership and political posturing, the federal government proved to be unready for shortages it had itself long predicted, and slow and ineffective in using its ample power to ramp up supplies. States, cities and health care providers, all of whom had trusted too much in federal preparation and taken too little responsibility for their own predictable needs, were left to scramble in an increasingly pricey competition with each other and the federal government.

In the short term, we can only demand that the president reverse course and put qualified, experienced professionals in the federal government squarely in charge of managing essential medical supplies. The president, if he is willing to put politics aside, has all the powers he needs to direct and equip competent career government staff with the necessary resources to fully use federal emergency and Defense Production Act authority to assess need and capacity, use investment and purchasing to incentivize manufacturers to increase production, and develop and implement a strategy for federal procurement and need-based distribution

to states. If the federal government fails to step up, states should continue to expand their use of cooperative mechanisms like interstate compacts to reduce cannibalistic competition in the medical supply market and to share resources as their relative needs rise and fall.

The best long-term solution for future emergencies is to be better prepared for the short-term need. As the COVID-19 emergency eases, Congress should fund and require HHS to hire and manage the long-term staff and infrastructure to monitor, track, and proactively address deficiencies in the supply chain for essential medical supplies. When the next virus hits, we should have complete, up-to-date information on the supply chain, an ample Strategic National Stockpile, and a real plan to meet the surge in demand.

Governments and the law also have a role in supporting the development of new devices, treatments and vaccines. FDA should immediately beef up its guidance on alternative sources and reuse of scarce medical supplies. Even more important is for Congress to look closely at the substantial risk that social or political pressure – or just the overwhelming desire to do good – will influence the FDA to approve a vaccine too soon. While expediting the process is obviously vital, it is equally important to ensure that the final decision is made by scientists, not politicians facing an election. In particular, FDA should resist pressure to issue an Expanded Use Authorization for any new vaccine, and the time is now for Congress to consider banning EUAs for COVID-19 vaccines altogether. States can use their authority over the practice of medicine to prevent practitioners from prescribing untested and potentially dangerous drugs even if the FDA has given them its green light.

Protecting Workers and Families

Before COVID-19, the U.S. lacked adequate protections to provide many low-income individuals and families safe and affordable housing and food security, and to ensure job and income security and worker safety. Additionally, changes in law and policy in the past few years have further limited health and safety protections and their enforcement. While the pandemic has affected all families and workers, the most severe impact has been on those the system was already failing – people of color and low-income individuals, whose ranks include the majority of workers providing essential services and unable to shelter at home. Stable housing, safe working conditions, food and income insecurity are all essential to health, and COVID-19 has made matters worse. Employers – and our society through our government – have done too little to protect essential workers and our vulnerable neighbors.

The many recommendations that flow from the assessment aim to address these socioeconomic determinants of health. Federal, state and local governments can all act to join our peer nations in providing universal, job-protected paid leave so that workers can afford to comply with quarantine and stay-at-home orders. The federal government can increase SNAP (food stamp) allotments, and widen eligibility for help. All levels of government can increase funding and widen eligibility for housing assistance of all kinds, and can maintain moratoria on evictions during and for a significant period of time after the COVID-19 crisis. OSHA can take more

vigorous action, with Congressional prodding if necessary, to make sure every workplace is safe from COVID and future pandemics.

Taking on Disparities and Protecting Equal Rights

The COVID-19 pandemic has laid bare the life-and-death consequences of inadequate and discriminatory laws and policies such as unequal worker protections, divisive immigration policies, and uneven access to health care, to name a few. Health and racial disparities are being compounded by the COVID-19 pandemic, the government's response (or lack thereof), and discrimination in the private sector. Existing gaps in legal protections, the lack of knowledge, and widespread noncompliance with current laws including Title VI of the 1964 Civil Rights Act, Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and Section 1557 of the Affordable Care Act (ACA), and others, are also contributing to COVID-19's impact. Additionally, the rollback of protections and access to services for immigrants and LGBT communities is contributing to the deepening of poverty, health disparities and lack of opportunity among these groups and their families. It is no surprise then that Black, Latinx, LGBT, persons with disabilities, incarcerated persons, and immigrants are disproportionately impacted by both the economic and health toll of the pandemic.

This assessment makes critical recommendations for the federal government to ensure that persistent health and racial disparities and inequities are not further exacerbated in the response to COVID-19 and beyond. At the federal level these recommendations include shoring up civil rights protections and offering clear guidance on various legal requirements, addressing immigrant and criminal justice detention and enforcement issues to minimize the spread of COVID-19, and solidifying or expanding resources and partnerships for organizations serving communities that are most at risk. Specifically, federal agencies such as the U.S. Department of Health and Human Services Office of Civil Rights should start by issuing clear, ongoing legal guidance on protections under the requirements of Title VI of the 1964 Civil Rights Act, Americans with Disabilities Act, Section 504 of the Rehabilitation Act, and Section 1557 of the ACA, and other federal legislation protecting civil rights. Congress should ensure sufficient resources for federal agencies to assist with the outreach and enforcement of these protections as well as encourage coordination with civil rights organizations to monitor compliance. Congress should also convene a commission or task force to study the causes of the racial and health disparities resulting from the COVID-19 pandemic to help assess future response policies. To minimize additional risks of exposure to COVID-19, Congress and the federal administration should order a halt to immigration detentions for nonviolent offenders, and specifically reduce or suspend enforcement around schools or health care facilities. To ensure these families are not further pushed to the brink of poverty, Congress or the federal administration should reverse the public charge rule to allow for access to critical food and health care services during this economic downturn. The federal administration or Congress should affirm and reinstate prohibitions on discrimination based on sexual orientation and gender identity in health care, housing and other private settings. Finally, Congress

IMPROVING PUBLIC HEALTH LAW CAPACITY

The many legal issues presented by COVID-19 — from lack of sufficient preparedness and attention to foreseeable challenges to the exercise of authority in response by public health officials across the nation and the disparate impact on certain populations — has underscored the need for increased capacity to use law and policy to protect the public's health and achieve health equity. Public health agencies should have funding for, and access to, public health law expertise, whether embedded in the agency or dedicated to the agency at municipal, county or state attorney general offices.

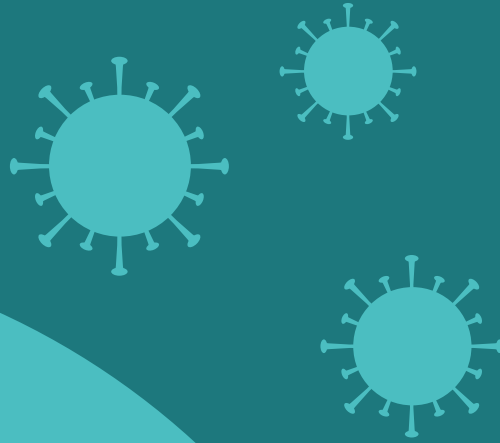
should ensure funding under the CARES Act or other federal emergency funding is available to community-based organizations serving racial/ethnic communities, immigrants, LGBT, incarcerated populations, persons with disabilities, and other under-resourced and underserved communities.

State governments have an important role in advancing equitable policies that can work towards eliminating or limiting health disparities at the local and state levels. State policymakers should incorporate equity considerations and address the needs of disenfranchised and underserved communities in COVID-19 response through state guidance to local and state agencies and departments. State agencies and attorneys general should clarify the rights and legal protections of people who experience discrimination under appropriate federal and state laws. As states roll out contact tracing applications and processes, they must ensure privacy protections, utilize best practices in reaching underserved communities, and include multilingual information and services. Additionally, state governments must ensure adequate resources for state and local level community-based organizations serving racial/ethnic communities, immigrants, LGBT, incarcerated populations, persons with disabilities, and other under-resourced and underserved communities. Further, states should allocate additional funding or realign budget priorities to include resources toward preventive health services.

Next Steps

COVID-19 is here now and there is no time to waste in getting it under control. Everyone in America can help by maintaining physical distance, wearing a mask, and vocally supporting an effective response rooted in apolitical good judgment, scientific evidence and public health expertise. Everyone in America can stand up for a response that is not just effective but fair and generous to essential workers and the vulnerable among us. This country is still capable of great things, and the legal recommendations in the Report offer a detailed roadmap to successful control of the pandemic and amelioration of its worst economic and social effects.

We cannot settle for less. 🌟



PART 1

**Using Government Powers to
Control the Pandemic**

Summary of Recommendations for Using Government Powers to Control the Pandemic

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Using Government Powers to Control the Pandemic* address basic public health measures such as physical distancing, travel bans and contact tracing. These recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal, state, local and Tribal guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic.

Action at the Federal Level

- To strengthen capacity and reduce political interference with scientific analysis, Congress should urgently consider legislation to reorganize the CDC as an independent agency, on the model of the Federal Reserve (Wiley, Federalism)
- To strengthen capacity and reduce political interference with scientific analysis, Congress should consider making FDA a stand-alone agency, outside of HHS (Zettler et al., Drug and Vaccine Development)
- Congress should amend the Public Health Services Act to add transparency and accountability mechanisms requiring the HHS Secretary and CDC Director to articulate the scientific basis for any guidance or orders issued pursuant to the authority provided by the Public Health Service Act to control the spread of communicable disease (Wiley, Federalism)
- Congress should fund and CDC should take the lead in developing a unified national approach to rapid testing, contact tracing, and isolation of people infected with COVID-19 (Gable, Mass Movement)
- CDC should develop rigorous, scientifically grounded, apolitical guidance for safe operation of schools, businesses, and indoor and other settings to assist government officials in making risk assessment decisions to prevent the spread of COVID-19 (Gable, Mass Movement)
- To assure the collection and dissemination of data necessary to guide public and private action,
 - o Congress should mandate and fund an effort to rebuild CDC's information infrastructure to ensure its disease surveillance reports and guidelines to governments, clinicians, businesses, private organizations, and individuals are accurate and free from political interference (Wiley, Federalism)
 - o Congress, HHS, or CDC should require enhanced demographic data collection as a condition of federal health care and public health funding, at all times, so that data regarding key identifying characteristics are collected consistently by state or local health departments (Huberfeld and Watson, Medicaid; Harris and Pamukcu, Civil Rights)
 - CDC should collect (and ask state and local agencies to collect) data regarding individuals' sexual orientation and gender identity This may, in part, be modeled on data collection in the National Health Interview Survey (Konnoth, Supporting LGBT Communities)
 - Congress should require HHS to collect and publicly report standardized data related to COVID-19 testing, infections, treatment, and outcomes including data disaggregated by disability status using data collection standards for disability that have been developed under the ACA (Pendo, Protecting the Rights of People with Disabilities)
 - o Agencies, including the CDC, should coordinate and standardize data collection efforts so that data sets can be effectively combined, and ensure that complete data is made publicly available and accessible to researchers (Harris and Pamukcu, Civil Rights; Anderson and Burris, Is Law Working)
- To facilitate appropriate use of technology in pandemic control, Congress should enact a statute that safeguards individuals from the risks that attend to digital COVID-19 contact tracing applications. Legislation should
 - o Ensure user privacy
 - o Assure informed, voluntary participation
 - o Respect user autonomy
 - o Prohibit discrimination and the dissemination of collected information to non-public health authorities
 - o Prescribe the commercial use of collected data, mandate government transparency and accuracy, guarantee data security
 - o Include a sunset provision
 - o Extend to users a privacy right of action (Oliva, Surveillance)

- The federal government should base travel bans on epidemiological factors, rather than nationality or immigration status (Parmet, Immigration)
- CDC should repeal its new interim final rule and base exclusion orders on the risk presented by travelers rather than their nationality. CDC's orders should not be used to override asylum laws (Parmet, Immigration)

Action at the State Level

- State legislatures should amend or enact new public health legislation clarifying the scope and authority of state officials to limit person-to-person interaction and impose closures, movement restrictions, gathering bans, and physical distancing requirements (Gable, Mass Movement)
- In the face of rising rates of infection and increasing community spread, governors and legislators should use their police power to
 - o Continue to promote physical distancing with measures that include incentives, supportive programs, and legal protections that support compliance and reduce inequitable disparate impact of gathering restrictions and closures (Gable, Mass Movement; Anderson and Burris, Is Law Working)
 - o Require mask wearing where strict physical distancing restrictions are relaxed or inapplicable
 - Mask wearing in settings where physical distance cannot be maintained, and voluntary reduction of social contacts, would be sensible for everyone to maintain for the foreseeable future regardless of legal requirements (Anderson and Burris, Is Law Working)
- State legislatures should fund, and state health departments should implement and/or contract for robust, ongoing contact tracing systems that
 - o Are closely connected to the communities they serve, including employment of a culturally diverse and sensitive workforce
 - o Engage existing community-based organizations to facilitate connection with diverse local communities and service needs
 - State health departments, in their implementation of contact tracing training and programs, should seek to identify and address unique barriers and concerns that may arise with outreach and service provision efforts to immigrant and migrant populations, including issues associated with immigration and public charge rules
 - State health departments should develop and implement expanded, multi-lingual health communication efforts to boost public trust and participation in, and awareness of, contact tracing initiatives
 - o Ensure those testing positive and identified as close contacts have access to health care, mental health, social services, and employment and housing protections needed for effective SARS-CoV-2 treatment and quarantine
 - o Include regular reporting to the public on contact tracing outreach and case ascertainment efforts (Silverman, Contact

Tracing; see also Gable, Mass Movement and Anderson and Burris, Is Law Working)

- Every emergency declaration should include the following information:
 - o Specific epidemiological data supporting the order
 - o Specific requirements for social distancing and mask wearing
 - o An explanation of why the order is needed
 - o An explanation of why the order does not violate personal freedoms (Jacobson et al., Executive Decision Making; Wiley, Federalism)
- Governors must protect public health officials from any threats to their health and safety (Jacobson et al., Executive Decision Making)
- Legislators should mandate and provide sufficient funding to support improved data collection efforts across agencies and departments to ensure critical demographic data is collected and analyzed to properly inform policy decisions (Harris and Pamukcu, Civil Rights)
 - o State health departments should follow the lead of Pennsylvania and California in collecting data on sexual orientation and gender identity (Konnoth, Supporting LGBT Communities)
 - o Pursuant to federal direction or on their own initiative, states should require the collection and public reporting of standardized data related to COVID-19 testing, infections, treatment, and outcomes including data disaggregated by disability status, using data collection standards for disability that have been developed under the ACA (Pendo, Protecting the Rights of People with Disabilities)
- In the absence of federal action to facilitate appropriate use of technology in pandemic control, states should enact a statute that safeguards individuals from the risks that attend to digital COVID-19 contact tracing applications. Legislation should
 - o Ensure user privacy
 - o Assure informed, voluntary participation
 - o Respect user autonomy
 - o Prohibit discrimination and the dissemination of collected information to non-public health authorities
 - o Prescribe the commercial use of collected data, mandate government transparency and accuracy, guarantee data security
 - o Include a sunset provision
 - o Extend to users a privacy right of action (Oliva, Surveillance)

Action at the Local Level

- Local ordinances should authorize targeted and scientifically appropriate closure, movement, and physical distancing restrictions consistent with stopping the spread of COVID-19 in local communities, and local governments should use these powers as needed (Gable, Mass Movement)

- Every emergency declaration should include the following information: (Jacobson et al., Executive Decision Making)
 - o Specific epidemiological data supporting the order
 - o Specific requirements for social distancing and mask wearing
 - o An explanation of why the order is needed
 - o An explanation of why the order does not violate personal freedoms
- Mayors and county executives must protect public health officials from any threats to their health and safety (Jacobson et al., Executive Decision Making)
- Local governments should fund, and local health departments should implement and/or contract for robust, ongoing contact tracing systems that
 - o Are closely connected to the communities they serve, including employment of a culturally diverse and sensitive workforce
 - o Engage existing community-based organizations to facilitate connection with diverse local communities and service needs
 - State health departments, in their implementation of contact tracing training and programs, should seek to identify and address unique barriers and concerns that may arise with outreach and service provision efforts to immigrant and migrant populations, including issues associated with immigration and public charge rules
 - State health departments should develop and implement expanded, multilingual health communication efforts to boost public trust and participation in, and awareness of, contact tracing initiatives
 - o Ensure those testing positive and identified as close contacts have access to health care, mental health care, social services, and employment and housing protections needed for effective SARS-CoV-2 treatment and quarantine
 - o Include regular reporting to the public on contact tracing outreach and case ascertainment efforts (Silverman, Contact Tracing)
- Local governments should enact paid sick leave policies with anti-retaliation provisions to support and encourage workers to remain at home when they are experiencing COVID-19 symptoms (Skar, Will the Coronavirus Make Us Rethink Quality Care)
- Local health departments and other agencies should collect detailed data on the populations and geographies most affected by COVID-19 and use this data to effectively allocate resources to the most impacted people and places (Harris and Pamukcu, Civil Rights)
 - o Local governments should require the collection and public reporting of standardized data related to COVID-19 testing, infections, treatment, and outcomes including data disaggregated by disability status, using data collection standards for disability that have been developed under the ACA (Pendo, Protecting the Rights of People with Disabilities)
 - o Where possible, pursue coordinated regional data collection efforts (Harris and Pamukcu, Civil Rights; see also Hoss and Tanana, Upholding Tribal Sovereignty)

Action at the Tribal Level

- Tribal governments should consider incorporating culturally appropriate mechanisms in legal measures to contain the spread of COVID-19
- If not already in place, Tribal governments should consider passing a public health code that contemplates issues of health communications, quarantine and isolation, incident command systems, and a point of contact for public health issues for the Tribe (Hoss and Tanana, Upholding Tribal Sovereignty)
- Tribes should consider including the following information in emergency declaration:
 - o Specific epidemiological data supporting the order
 - o Specific requirements for social distancing and mask wearing
 - o An explanation of why the order is needed
 - o An explanation of why the order does not violate personal freedoms (See Jacobson et al., Executive Decision Making; Wiley, Federalism)
- Tribal governments must protect public health officials from any threats to their health and safety (See Jacobson et al., Executive Decision Making)
- In the absence of federal action to facilitate appropriate use of technology in pandemic control, Tribes should consider enacting a statute that safeguards individuals from the risks that attend to digital COVID-19 contact tracing applications. Legislation should
 - o Ensure user privacy
 - o Assure informed, voluntary participation
 - o Respect user autonomy
 - o Prohibit discrimination and the dissemination of collected information to non-public health authorities
 - o Prescribe the commercial use of collected data, mandate government transparency and accuracy, guarantee data security
 - o Include a sunset provision
 - o Extend to users a privacy right of action (See Oliva, Surveillance)

A Chronological Overview of the Federal, State, and Local Response to COVID-19

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SUMMARY. Since the first case of COVID-19 was confirmed in the United States, federal, state, and local governments have taken varying degrees of legal action to prevent the spread of the virus and mitigate its impact on the public's health and health care systems. Federal action has primarily consisted of national emergency declarations, travel bans, guidance on social distancing measures, and laws aimed at mitigating the economic impacts of COVID-19. Legal action at the state and local level has focused heavily on social distancing requirements and other emergency measures to reduce the spread of the virus, including stay-at-home orders, prohibitions on large gatherings, closures of non-essential businesses and schools, and the mandatory use of face masks. This Chapter provides an overview of these actions, chronicling the federal and state legal response from January to July 2020, and highlighting policy trends at the local level from March to July 2020.

Introduction

The World Health Organization (WHO) declared the 2019 outbreak of COVID-19 a pandemic on March 11, 2020. Although researchers believe isolated incidents of coronavirus hit the U.S. in December 2019, the first U.S. case of COVID-19 was confirmed by the Centers for Disease Control and Prevention (CDC) on January 21, 2020 – with cases totaling 2,624,873 and deaths reaching 127,229 as of July 1, 2020. Since its arrival, federal, state, and local governments have taken legal action to prevent the spread of COVID-19 and mitigate its devastating impact on population health.

The U.S. Federal Response to COVID-19

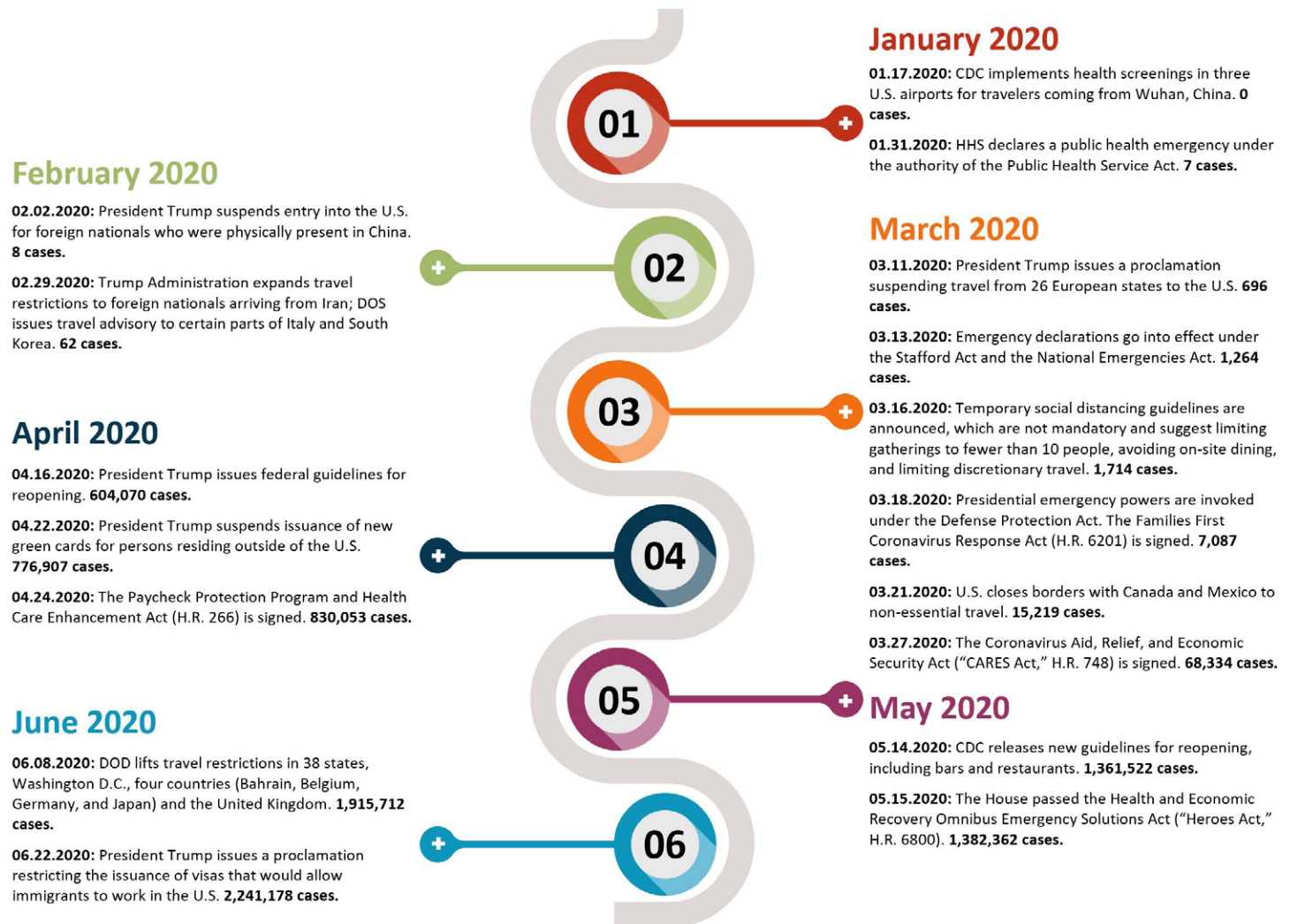
In times of national emergencies, the U.S. federal government has the broad legal authority to activate federal emergency powers to protect health and human life. Three primary sources of statutory authority – the Public Health Service Act, the Stafford Disaster Relief and Emergency Assistance Act (the Stafford Act), and the National Emergencies Act – allow the federal government to issue emergency declarations, which enables the release of funds and activates immediate response efforts to reduce the spread of a virus. Each of these has been activated in the wake of COVID-19; however, the chronology of these declarations exposes the delay in action in what could have been a united, sweeping, and life-saving federal response.

Figure 1.1 provides a timeline of the legal and regulatory actions the federal government took in response to the COVID-19 outbreak from

January 2020 through June 2020, including the respective national case counts (World Health Organization, 2020).

Together, the Public Health Service Act, the Stafford Act, and the National Emergencies Act trigger additional statutory powers that grant the government broad sweeping authority to rapidly deploy prevention and safety measures and respond to the financial needs of U.S. citizens. More specifically, the authority of Section 319 of the Public Health Service Act allows the Secretary of Health and Human Services (HHS) to declare a public health emergency, make grants, activate certain federal funds (e.g., the Public Health Emergency Fund), and investigate the cause, treatment, or prevention of a disease. The public health emergency initially declared on January 31, 2020, was renewed on July 23, 2020. Both the Stafford Act and the National Emergencies Act provide the federal government statutory authority to declare a national emergency. A national emergency declaration, as opposed to a public health emergency, directly empowers the president to activate certain presidential authority, such as the ability to activate the National Guard and seize control of the internet. In response to the COVID-19 pandemic, the declaration of a national emergency freed up \$50 billion in federal funds for states and territories, assisted with the allocation of medical resources across the country (see Chapter 24), initiated the emergency powers of the Federal Emergency Management Agency, and waived certain insurance provisions. Additional presidential powers were also invoked under the Defense Production Act, including the ability

Figure 1.1: A chronology of the U.S. federal response to COVID-19, January – June 2020.



to allocate materials (e.g., the production and distribution of ventilators), services, and facilities as needed to assist in public defense (see Chapter 23).

In addition to exercising existing statutory power, the federal government passed new laws in response to COVID-19. The Families First Coronavirus Response Act (H.R. 6201) was signed to fund free coronavirus testing, provide extended family medical leave and paid sick leave for workers, and expand unemployment benefits. The Act temporarily expanded the Family Medical Leave Act by covering leave for an employee who is unable to work or telework because they need to care for a child under 18 if the child's school or daycare is closed due to COVID-19. This Act also required employers with fewer than 500 employees to provide paid sick leave for employees unable to work due to medical advice, a government quarantine or isolation order, caring for others under a government order, seeking medical treatment for COVID-19 symptoms, or caring for children at home due to school or daycare closures. The Coronavirus Aid, Relief, and Economic Security (CARES) Act (H.R. 748), a \$2 trillion stimulus bill, provided direct payments to eligible individuals with income of less than \$99,000, or individuals with a household income of less than \$198,000. The

CARES Act also included substantial funding for small business relief (\$375 billion) through the Paycheck Protection Program and Healthcare Enhancement Act (H.R. 266), expanded unemployment benefits (\$260 billion), and suspended federal student loan repayments without interest until September 30, 2020.

While the federal government took legal measures to stimulate the economy, issue international travel bans, and provide discretionary guidance and expertise, state and local governments used their authority to issue a wide array of mandatory social distancing requirements in an effort to mitigate the spread of COVID-19.

The U.S. State Response to COVID-19

The Center for Public Health Law Research (CPHLR) at Temple University's Beasley School of Law is tracking COVID-19 emergency declarations and mitigation policies at the state level from January 20, 2020 through July 1, 2020 (Center for Public Health Law Research, 2020). CPHLR is utilizing a rapid assessment policy surveillance process to expedite the publication of open-source longitudinal data, accompanied by direct legal citations and full text versions of the state orders for all 50 states and the District of Columbia. By July 1, 2020, the states had collectively made more

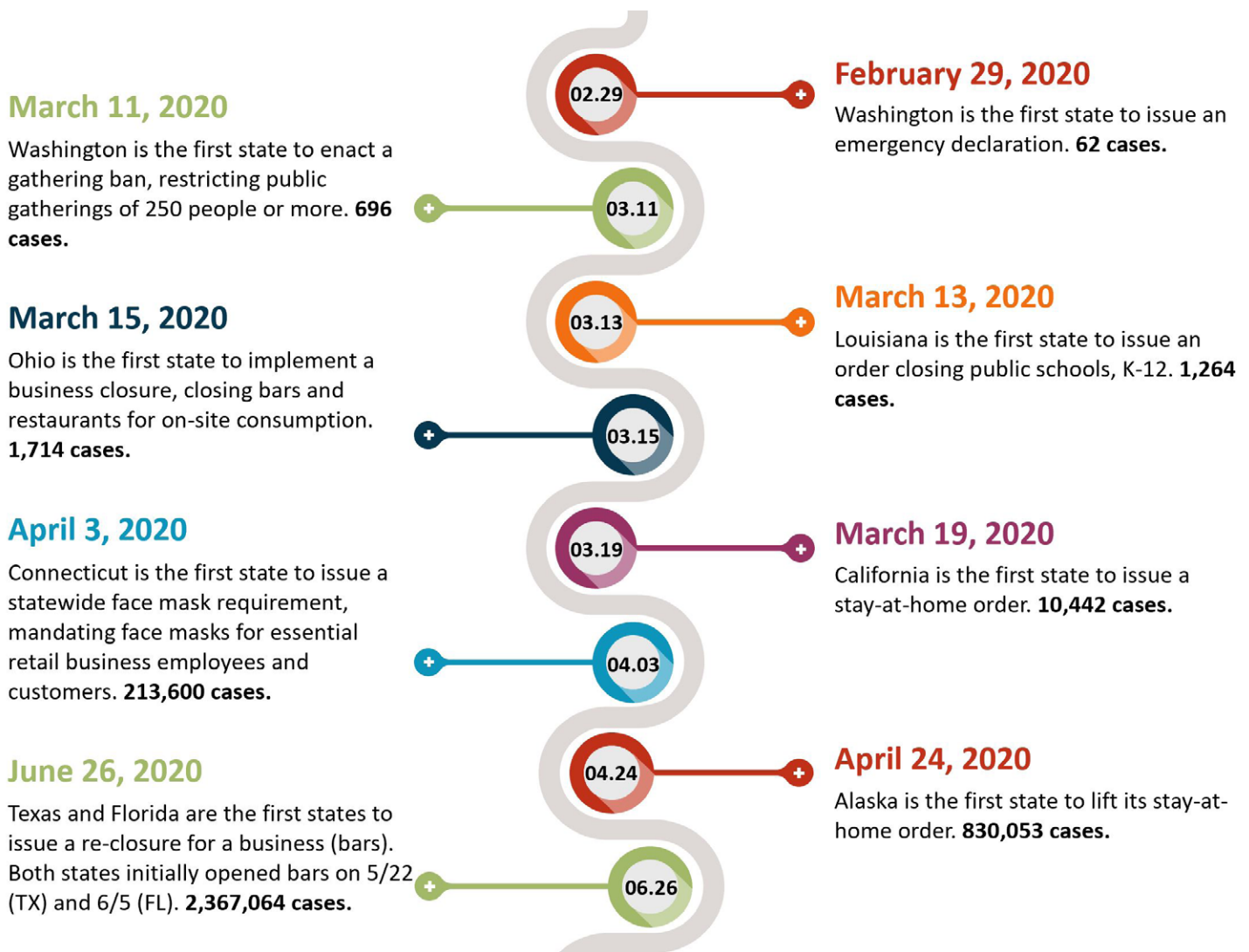


Figure 1.2: A chronology of the first states to issue select measures in response to COVID-19, February – June 2020.

than 1,000 legal changes, including emergency declarations, travel restrictions, stay-at-home orders, business closures, gathering bans, elective medical procedure restrictions, and face mask requirements. Figure 1.2 provides a timeline of the first states to implement certain measures, along with the corresponding national COVID-19 case numbers as reported by the WHO.

Washington was the first state to declare an emergency due to COVID-19 on February 29, 2020. Similar to declaring an emergency at the federal level through the National Emergencies Act, state emergency declarations activate the power of the state executive or the state health officer to suspend or waive regulatory rules, streamline administrative procedures, or expend emergency funds. By March 16, 2020, all 50 states and the District of Columbia had issued an emergency declaration. Figure 1.3 shows the daily progression of the state emergency declarations that were issued between February 28, 2020 and July 1, 2020.

Once declaring an emergency, states began to issue mitigation policies at a rapid pace of just about every day. State governors

began announcing statewide school closures, and by March 20, 2020, 39 states and the District of Columbia closed K-12 public schools by executive order. These initial closures were intended to last for a matter of weeks, only to later be extended through the end of the school year by subsequent executive orders. On March 19, 2020, California started a trend of statewide stay-at-home orders. Within the subsequent two weeks, 32 more states and the District of Columbia issued statewide stay-at-home orders, as depicted in Figure 1.4. The remaining six states implemented stay-at-home orders by April 7, 2020, while Arkansas, Connecticut, Iowa, Kentucky, Massachusetts, Nebraska, North Dakota, Oklahoma, South Dakota, Texas, Utah, and Wyoming never issued explicit statewide stay-at-home orders as of July 1, 2020.

By April 1, 2020, 47 states and the District of Columbia issued various orders closing non-essential businesses statewide, which may include retail businesses, bars, restaurants, entertainment businesses (e.g., movie theaters, concert halls), gyms, and personal service businesses (e.g., hair salons, barber shops). Other state actions included restrictions on elective medical procedures,

Figure 1.3: New statewide emergency declarations by the day, February 28, 2020 – July 1, 2020.

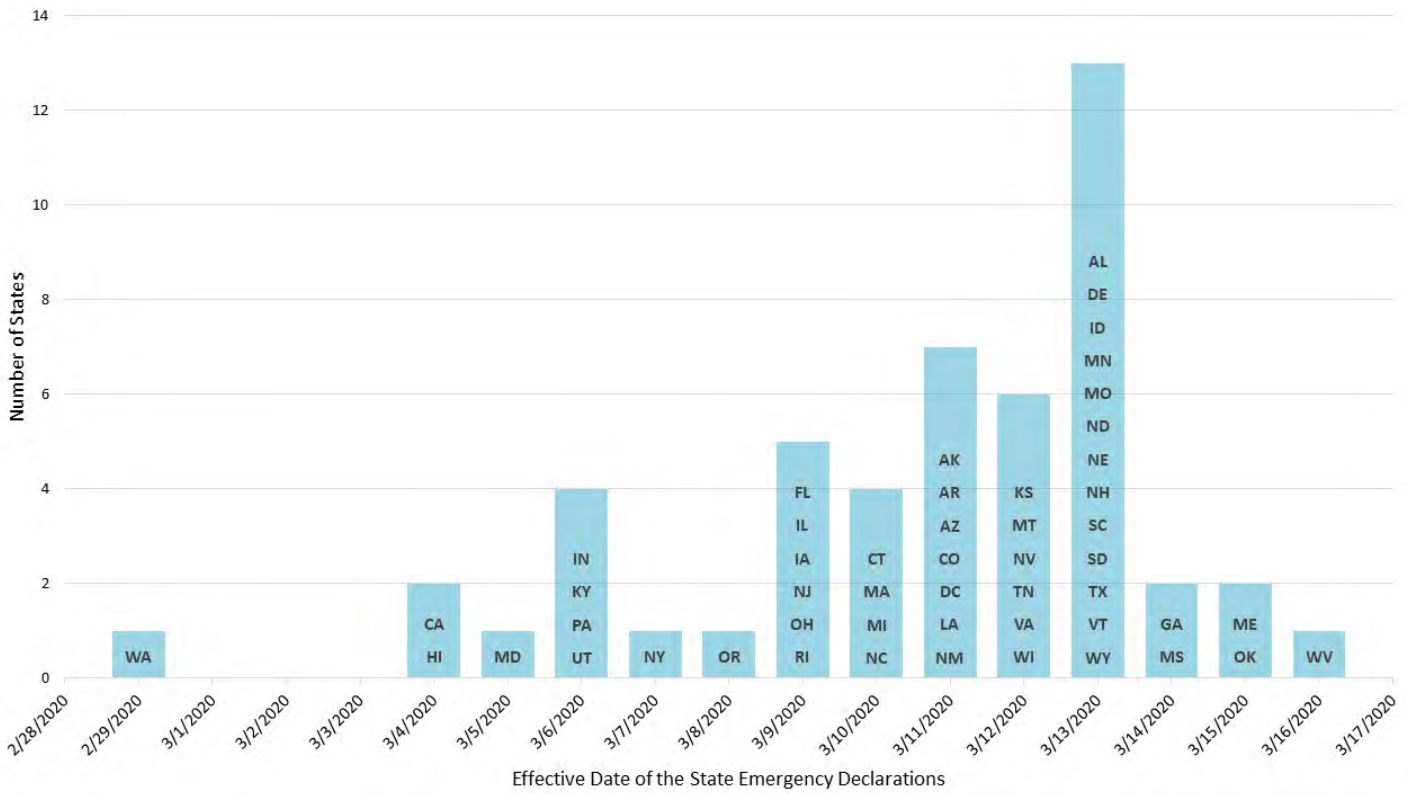


Figure 1.4: New statewide stay-at-home orders by day, March 18, 2020 – July 1, 2020.

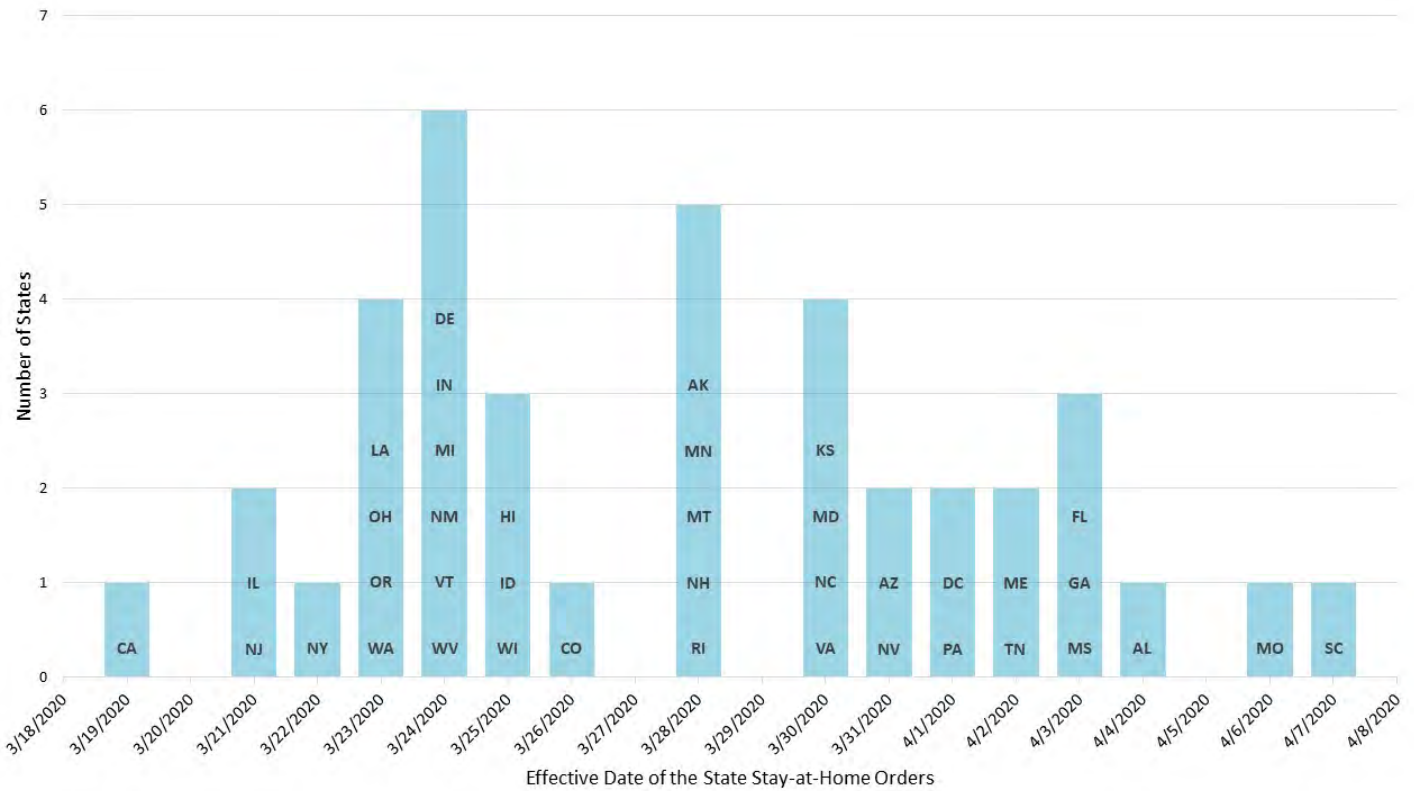
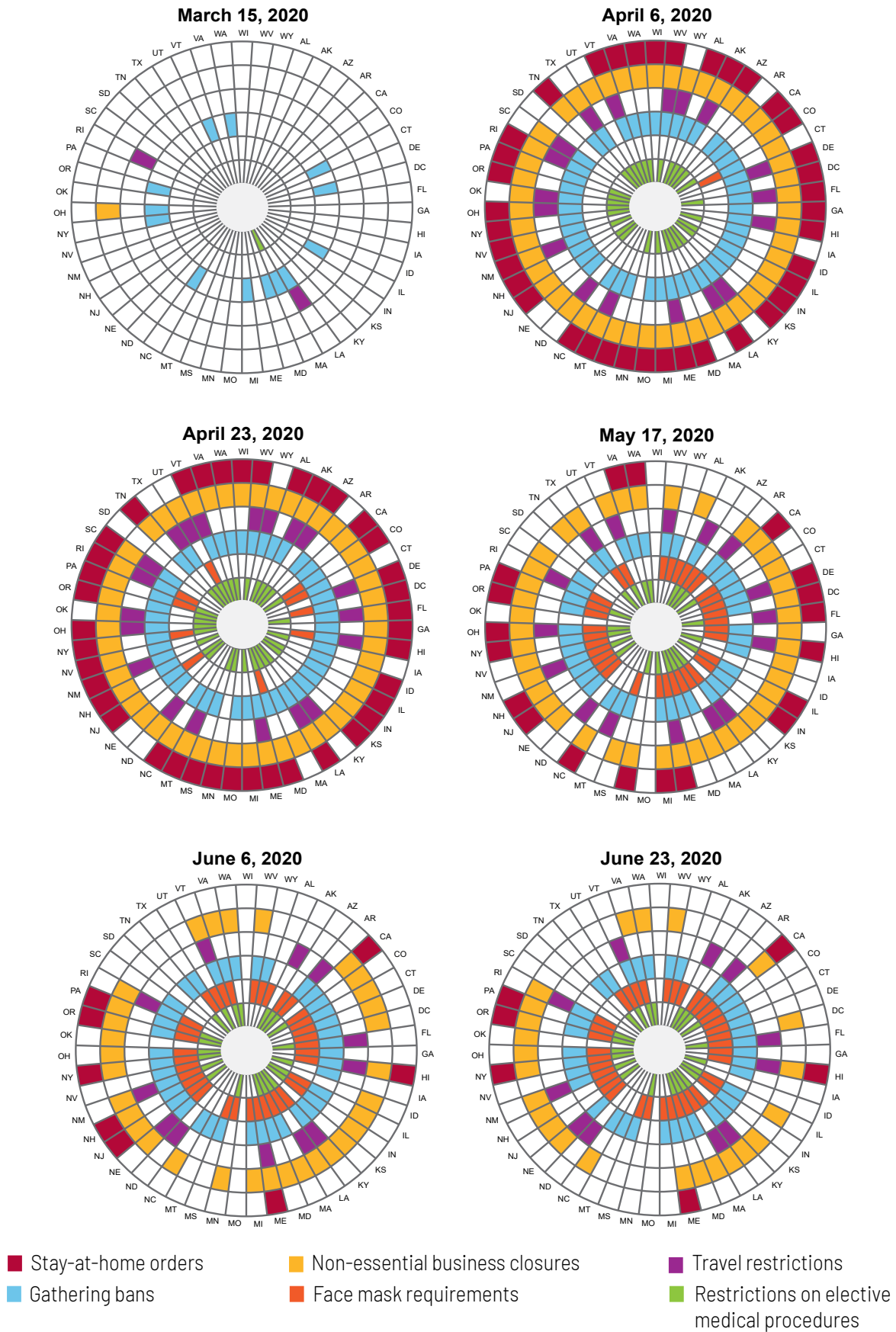


Figure 1.5: State COVID-19 mitigation measures, March 15, 2020 – June 23, 2020.



including abortion, and temporary policies for correctional facilities to limit physical contact and mitigate spread (see Chapters 15 and 31). State action also extended to housing issues by imposing temporary moratoriums on eviction and foreclosure proceedings, as well as utility and water shutoffs (The Eviction Lab, 2020) (see Chapter 25). In terms of legislation, state legislatures passed appropriations bills, created unemployment relief programs, and amended state telehealth laws to increase access to care (see Chapter 16).

Between March 11, 2020 and April 11, 2020, 20 states instituted restrictions on travelers, 12 of which required all travelers entering the state to self-quarantine for 14 days. Six of these states required people entering the state from early hotspot states, like New York, New Jersey, and Connecticut to quarantine for 14 days. As of June 1, 2020, only 12 states still had restrictions on travelers. By late June, due to the emerging hotspots in the South and Southwest, and the decrease of new cases in the Northeast, the travel restrictions traded places as the original hotspot states of New York, New Jersey, and Connecticut began issuing advisories for travelers from states like Arizona, Texas, and Florida (Stracqualursi, 2020).

Between January 20, 2020 and July 1, 2020, states enacted mitigation policies covering at least six major topics, including stay-at-home orders, gathering bans, non-essential business closures, face mask requirements, travel restrictions, and restrictions on elective medical procedures. The charts in Figure

1.5 provide snapshots of these legal measures at approximately three-week intervals between March 15, 2020 and June 23, 2020. The highpoints for almost all of these legal measures occurred during the month of April: as of April 6, 2020 and April 23, 2020, 50 states issued a business closure order and 46 states issued gathering bans. As of April 23, 2020, 39 states issued explicit stay-at-home orders, 20 states had travel restrictions in place, and 31 states restricted elective medical procedures. As states began to reopen, they started to implement face mask requirements, with 37 states requiring individuals in public settings, customers, or employees to wear face masks as of June 23, 2020.

Beginning in late April, states began to relax restrictions. After the White House issued guidelines for reopening on April 16, 2020, states started developing their own reopening plans. Alaska was the first state to lift its stay-at-home order on April 24, 2020. By June 22, 2020, 34 states and the District of Columbia explicitly lifted their stay-at-home orders. Figure 1.6 shows the progression of states explicitly lifting stay-at-home orders through July 1, 2020 alongside the total number of national COVID-19 cases, according to the WHO.

From mid-April through the beginning of May, states implemented reopening plans often with county- or region-specific phases, allowing certain types of businesses (e.g., personal service businesses and fitness centers) to reopen at a reduced capacity following strict social distancing measures. After a spike in cases in late June, however, some states like Texas paused their reopening

Figure 1.6: Total number of states explicitly lifting stay-at-home orders (left y-axis) with the total number of COVID-19 cases in the U.S. (right y-axis), April 23, 2020 – July 1, 2020.

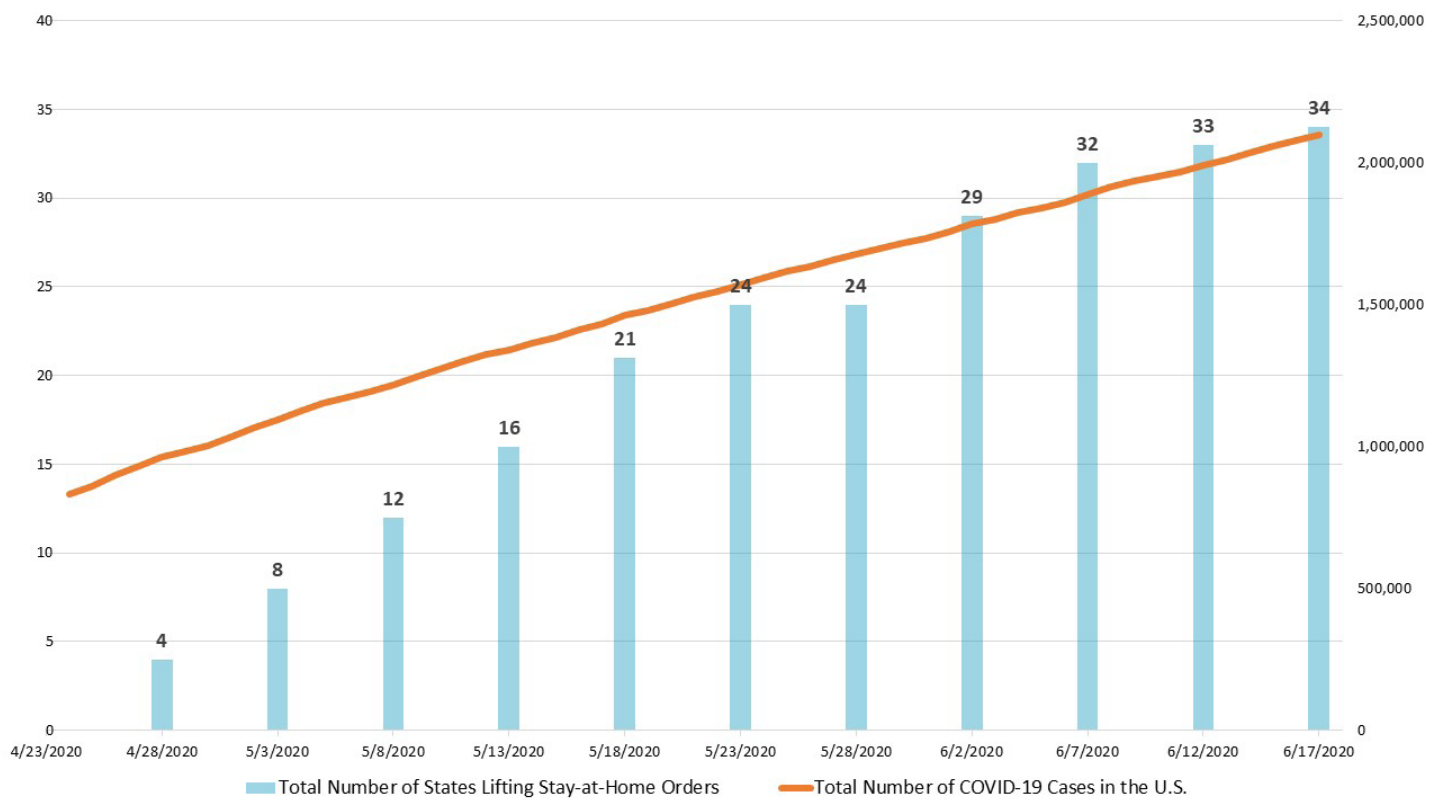
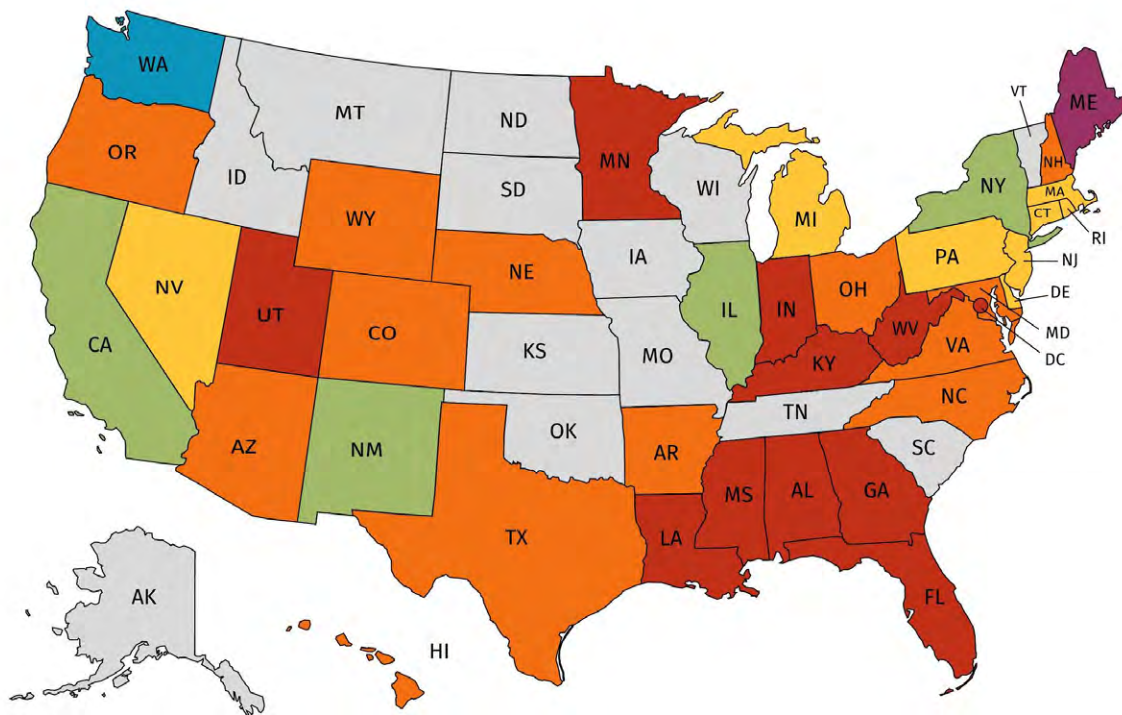
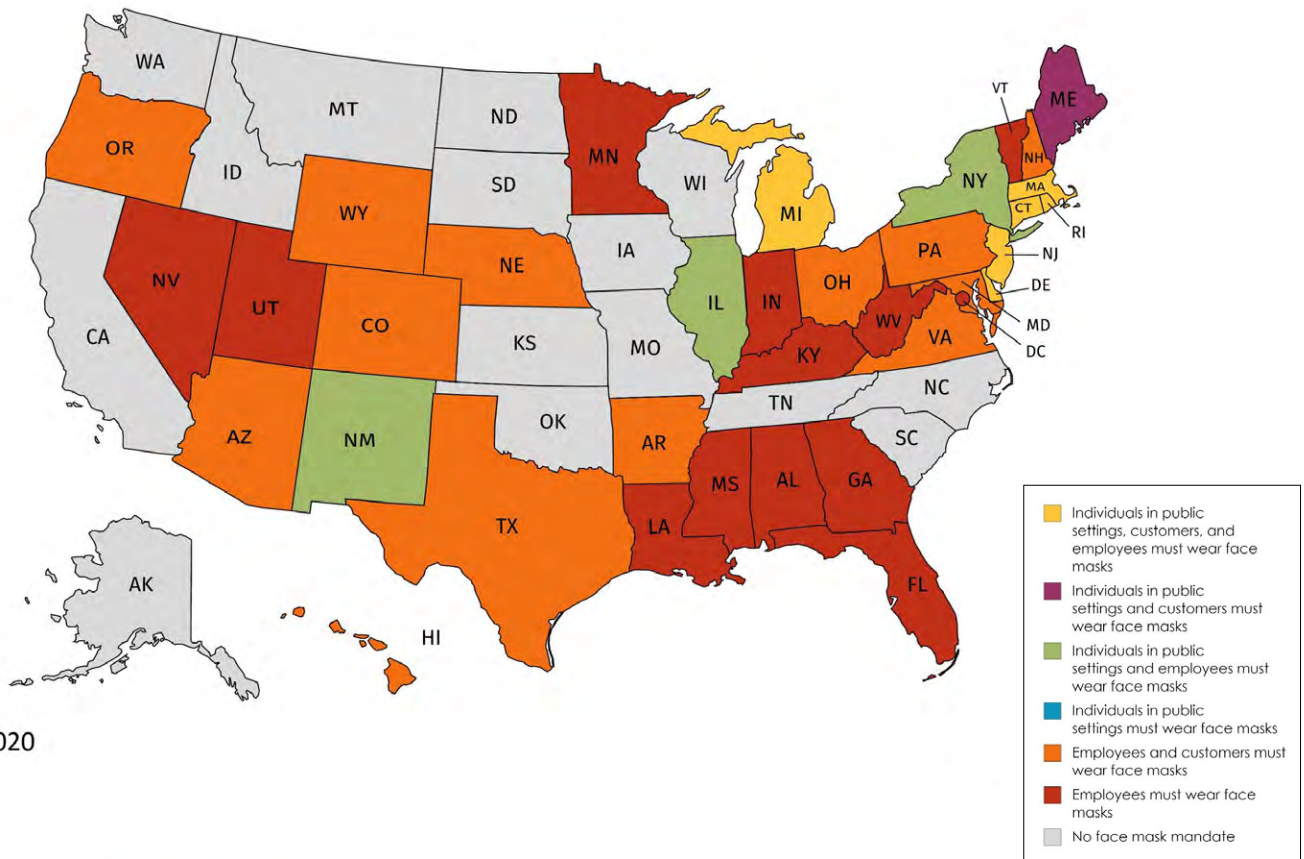


Figure 1.7: State emergency orders requiring face mask use on June 1, 2020 and July 1, 2020.



plans by delaying plans for indoor dining or re-instituting closures. By July 1, 2020, five states began to re-close bars, movie theaters, and gyms.

With the stay-at-home orders lifting and businesses reopening, states began to require people to wear face coverings in public places, while taking public transportation, or while shopping at newly reopened retail businesses. As of June 1, 2020, 36 states had some type of face mask mandate in place, six of which required individuals in public settings, customers, and employees to wear face masks. By July 1, 2020, 38 states had a face mask mandate, with eight states requiring individuals in public settings, customers, and employees to wear face masks, as illustrated in Figure 1.7.

During the COVID-19 outbreak, states explicitly preempted local governments from enacting specific mitigation policies, or superseded local orders covering the same subject matter in the state order. Preemption is a legal doctrine that allows a higher level of government to restrict, or prevent, the authority of a lower level of government (see Chapter 9). As of June 1, 2020, 18

states blocked local action by preempting county, municipal, or tribal governments. For example, the Mississippi stay-at-home order blocked local authorities from enforcing more restrictive orders, which required cities to cancel earlier issued city-level mitigation measures (Davidson & Haddow, 2020). States also exerted their power over localities in the absence of explicit preemption provisions. For instance, the governor of Nebraska told counties they would not receive money under the federal CARES Act if they required people to wear masks in government buildings (Mena, 2020). On the other hand, as of June 1, 2020, 17 states expressly allowed local governments to impose more restrictive requirements that went beyond state measures. Further, states have also both blocked and permitted local action. For example, the governor of Arizona partially reversed his previous preemption mandate, allowing local officials to set face mask requirements, but maintained the preemption impacting other business restrictions (Local Solutions Support Center, 2020).

The U.S. Local Response to COVID-19

The local level emergency response to COVID-19 includes policies issued by municipalities and counties aimed at reducing the spread

Figure 1.8: A chronology of select municipal measures in response to COVID-19, March – June 2020.

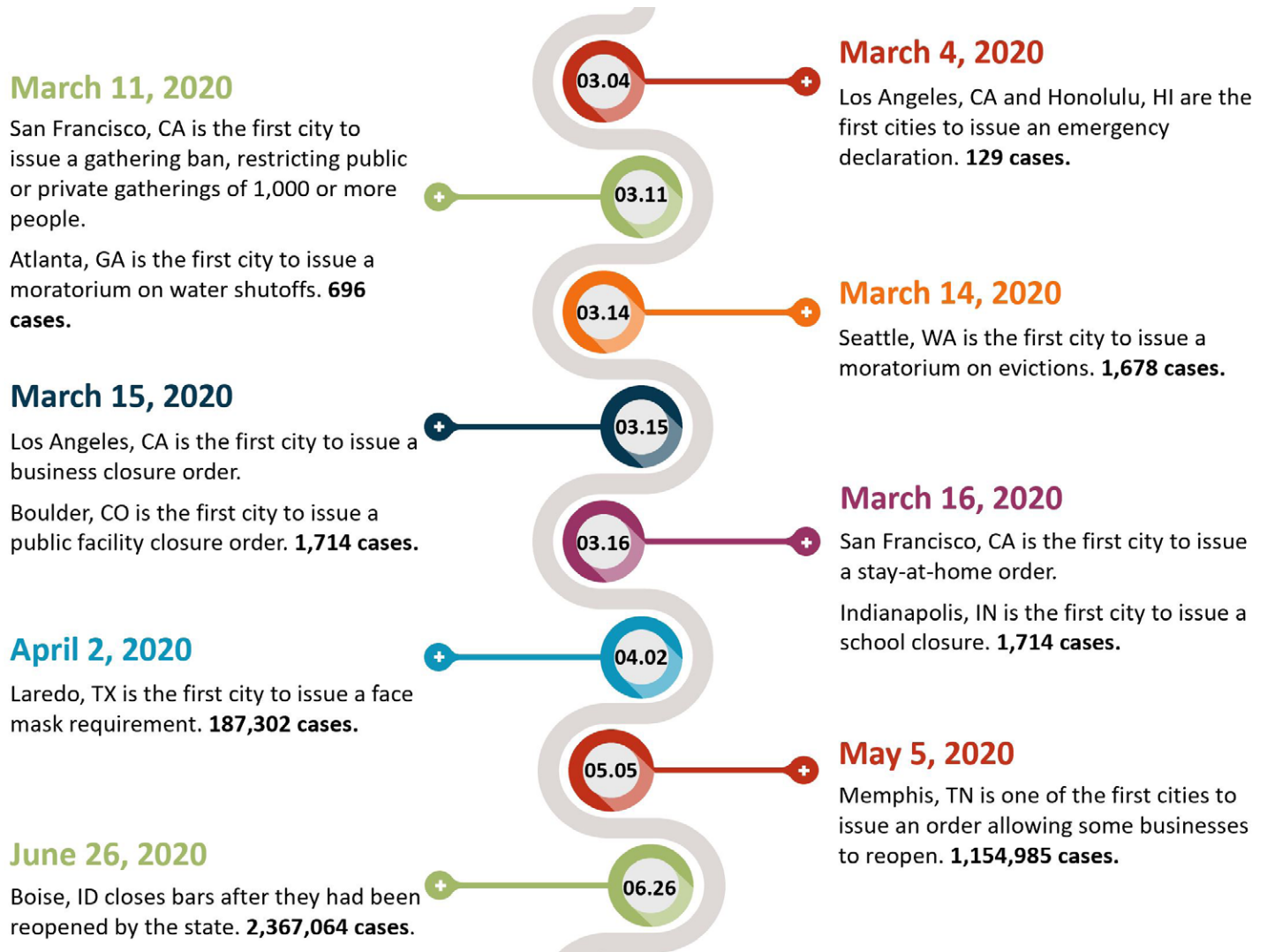
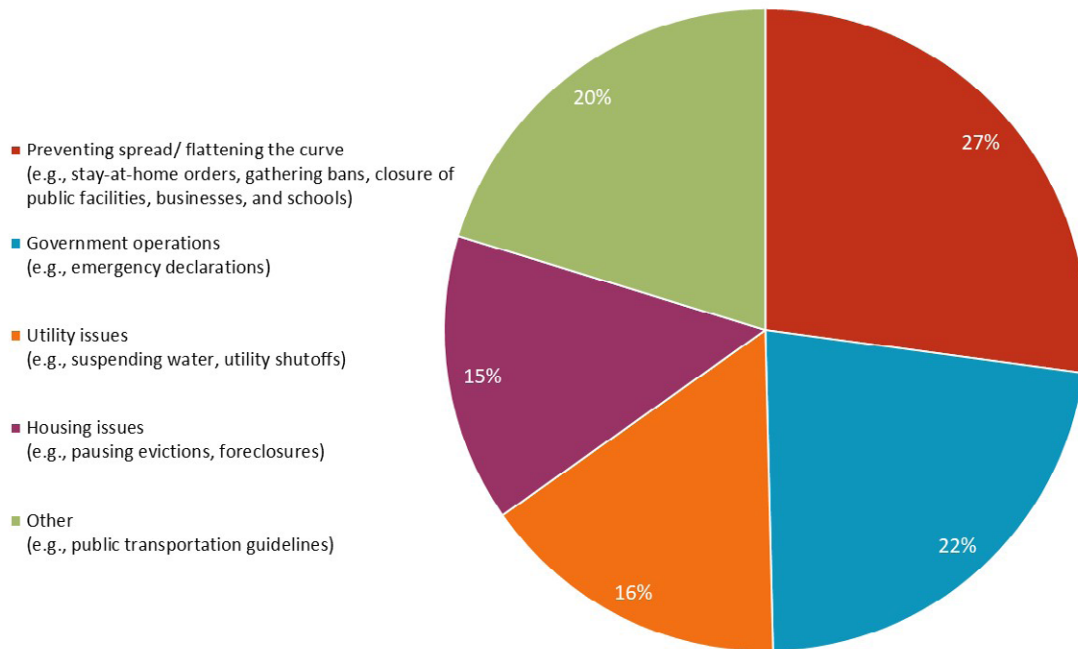


Figure 1.9: Types of COVID-19 municipal policies in the U.S., March – June 2020.



of the virus and mitigating the economic impact on residents. Localities have taken many of the same measures as the states, by issuing emergency declarations, stay-at-home orders, and business closure orders. As of April 15, 2020, at least 864 counties had issued an emergency declaration, and at least 169 counties had established either a safer-at-home or a business closure policy (National Association of Counties, 2020). As of July 1, 2020, at least 511 cities had established one or more policies in response to the COVID-19 outbreak.

Figure 1.8 provides a timeline of the first cities to implement certain measures along with the corresponding national COVID-19 case numbers as reported by the WHO. The policy information included in the timeline is based on data from the National League of Cities (NLC) which could be independently verified by CPHLR (National League of Cities, 2020).

In addition to issuing emergency declarations and closure orders, cities established other types of measures, including temporarily suspending evictions, temporarily suspending water and utility shutoffs, and addressing public transportation issues. Figure 1.9 illustrates the composition of the primary types of municipal policies that were issued in response to COVID-19 using the data tracked by NLC (National League of Cities, 2020).

Other types of local-level response include: government actions to protect incarcerated individuals, including ordering the release of people in jail; providing emergency paid leave for workers not covered by the federal Families First Coronavirus Response Act; and protecting access to food, including defining essential services to include food banks, and defining essential activities to include obtaining or providing fresh food (A Better Balance, 2020; Healthy Food Policy Project, 2020; Prison Policy Initiative, 2020). Local policies, when not preempted, may establish additional measures that are not required by the federal or state responses to COVID-19.

Conclusion

The U.S. legal response to the COVID-19 outbreak was comprised of a range of actions taken by the federal, state, and local governments. The federal government exercised its statutory authority to declare a national emergency, which allowed the government to release funds and initiate immediate response efforts. The federal government also issued guidance regarding social distancing and reopening measures. State and local governments went beyond issuing permissive guidance and established mandatory social distancing requirements. States and localities issued orders or proclamations requiring residents to stay home, closing businesses and schools, banning large gatherings, and requiring the use of face coverings. Among other measures, state and local governments also acted to temporarily suspend evictions, foreclosures, and utility and water shutoffs.

New state mitigation orders appeared almost daily between mid-March and early April. Legal activity began with closures and social distancing restrictions, then moved towards easing those measures and reopening businesses. With the resurgence of COVID-19 cases in June, states put reopening plans on hold, reverted to stricter mitigation policies, or even closed newly reopened businesses, as was the case in seven states by July 1, 2020. Many localities also established measures in response to COVID-19, with more than 850 counties and 500 cities having done so by July 1, 2020.

The legal response at the federal, state, and local level to COVID-19 has been unprecedented and continues to rapidly evolve across the United States. 🌞

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References

- A Better Balance. (2020). Emergency Paid Sick Leave Tracker: State, City, and County Developments. Retrieved July 30, 2020, from <https://www.abetterbalance.org/resources/emergencysickleavetracker/>
- Center for Public Health Law Research. (2020). COVID-19: State Emergency Declarations & Mitigation Policies. Retrieved July 30, 2020, from <https://lawatlas.org/datasets/covid-19-emergency-declarations>
- Davidson, N. M. & Haddow, K. (2020, June 22). State Preemption and Local Responses in the Pandemic. Retrieved July 30, 2020, from <https://www.acslaw.org/expertforum/state-preemption-and-local-responses-in-the-pandemic/>
- Healthy Food Policy Project. (n.d.). Local Government Policies to Support Food Access During the COVID-19 Pandemic – An Index. Retrieved July 30, 2020, from <https://healthyfoodpolicyproject.org/resources/index-of-local-government-policies-for-to-support-food-access-during-the-covid-19-pandemic>
- Local Solutions Support Center. (2020). At A Glance: Preemption and COVID-19. Retrieved July 30, 2020, from <https://static1.squarespace.com/static/5ce4377caeb1ce00013a02fd/t/5f0c8eb6b3bec83e78852580/1594658487035/covid+masks+7.12.pdf>
- Mena, K. (2020). Nebraska Governor Tells Local Officials They Can't Require Face Masks If They Want Federal Coronavirus-Relief Funding. Retrieved July 30, 2020, from <https://www.cnn.com/2020/06/19/politics/nebraska-governor-no-face-masks-requirement/index.html>
- National Association of Counties. (2020). COVID-19 Pandemic Response: County Declaration and Policies. Retrieved July 30, 2020, from <https://ce.naco.org/?dset=COVID-19&ind=Emergency%20Declaration%20Types>
- National League of Cities. (2020). COVID-19: Local Action Tracker. Retrieved July 30, 2020, from <https://coviYed19.nlc.org/resources/covid-19-local-action-tracker/>
- Prison Policy Initiative. (2020). Responses to the COVID-19 Pandemic. Retrieved July 30, 2020, from <https://www.prisonpolicy.org/virus/virusresponse.html>
- Stracqualursi, V. (2020). NY, NJ, and CT Expand Quarantine Advisories for Travelers From 8 More States with High Coronavirus Rates. Retrieved July 30, 2020, from <https://www.cnn.com/2020/06/30/politics/travel-advisory-coronavirus-new-york-new-jersey-connecticut-massachusetts/index.html>
- The Eviction Lab. (2020). COVID-19 and Changing Eviction Policies Around the Nation. Retrieved July 30, 2020, from <https://evictionlab.org/covid-eviction-policies/>
- World Health Organization. (2020). United States of America. Retrieved July 30, 2020, from <https://covid19.who.int/region/amro/country/us>

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Is Law Working? A Brief Look at the Legal Epidemiology of COVID-19

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SUMMARY. Legal intervention has featured prominently in the response to the COVID-19 pandemic. In most places in the world, the legal response has consisted of some combination of traditional disease control measures (individualized testing, contact-tracing, distancing), population-based physical distancing (including school and business closures, stay-at-home orders, gathering bans and masking rules), travel strictures (including travel bans, border closures and quarantines), and economic support measures (which are beyond the scope of this Chapter). Researchers have tried to guide that response in real-time by measuring rapidly changing legal interventions and assessing their current and future effects. In a moment when law can have huge beneficial and deleterious effects, this legal epidemiology can fairly be regarded as a crucial element of the overall COVID-19 response. This Chapter tries to identify important take-aways from this evolving evidence base. The epidemiologic record shows that the U.S. is failing to control the virus, but little else is as clear. Understanding how much better or worse things would be with different legal interventions is complicated given that the effects of rules are dependent on settings (e.g., density), timing (e.g., in relation to population transmission rates), and social context (e.g., social norms and political conditions). It is difficult for researchers to untangle the effects of specific legal requirements, let alone to identify some ideal set of least restrictive elements. Nevertheless, previous experience, prevailing theory, and some direct evidence suggest that some early and aggressive distancing interventions have important benefits. Questions of costs, disparities and side effects remain largely unanswered.

Introduction

By definition, pandemics spread widely and rapidly. The public health response seeks to reshape behavior and environments to drive down transmission. Law is an apt tool for defining the behavior society requires of people and institutions. Widespread adoption reshapes the social and physical environment towards less vulnerability, which in turn can induce more people and organizations to change their behavior. In short order, a nation where only a few people wore masks and lots of people hung out in bars can become a nation where most people cover their faces and are leery about sitting in crowded restaurant. These legal effects are not automatic. Laws are often ineffective, and laws can be harmful and have inequitable effects. Research to learn what laws work, what laws harm, and how they do it, is essential to guiding policy and practice, even in the short run.

As this Report describes, we are seeing new legal rules for matters as varied and important as methadone treatment and eviction. We have also been forced to see again the often harsh inequities

in seemingly neutral laws: the economic relief in the CARES Act, for example, assumes that people have filed tax returns and that businesses have banks, both of which are less true for Black people and their businesses. These are important to study for effects on health, equity and the path of the epidemic. Most research, however, and this Chapter, has concerned the measures aimed directly at infection. We begin by suggesting some important questions to ask about how law works, which can inform the reading of research findings. We conclude with some practical takeaways for action in the next few months.

Judging the Effectiveness of Law: Keeping Theory and Logic in Mind

The idea of law as rules is a simple one, but the way law works to change behavior and environments is complicated. In the COVID-19 response, law is being used to instigate major changes in how individuals go about their daily lives as social and economic beings, and to rewrite many of the usual rules and procedures of organizations and systems. The obvious research questions, then,

are whether laws requiring, for example, public mask-wearing, cause people to wear masks in public, and whether they have an inequitable impact (for example, is there disparate enforcement) or unexpected costs (for example, exacerbating shortages in healthcare settings).

In the mad rush of COVID-19, research on the effects of the legal response faces limitations of data, research design and inference. Well-established theory can help in both conducting and consuming research on the COVID-19 legal response, and suggests four particularly useful questions underlying legal impact:

1. Do the targets of the rule actually understand what it requires them to do?
2. Are they able to comply?
3. Are they willing to comply?
4. What will be done to detect and correct non-compliance, or to support compliance?

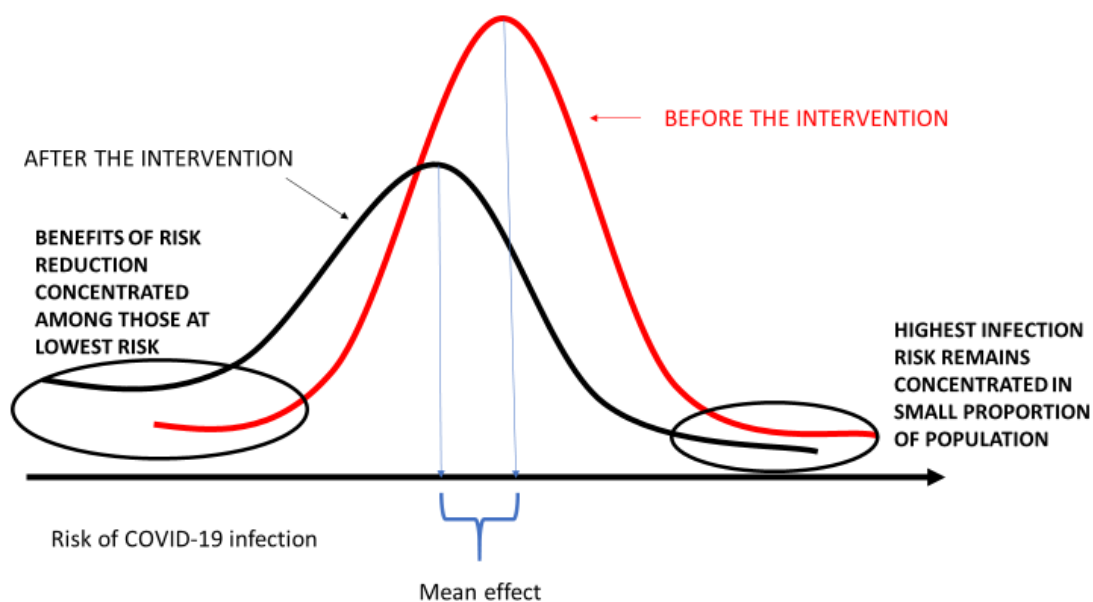
People can't follow rules they don't know about or understand. In emergency response, this problem arises often in complicated regulatory matters like whether a doctor from New York can volunteer at a hospital in Connecticut. Regulatory compliance in emergencies is worthy of serious study, but does not figure prominently in the early COVID-19 research. Many rules, like those closing schools, are unambiguous, and so researchers can assume that most targets of the law know most of what is being required of them. Laws closing schools also are effectively self-enforcing: closing schools, closes schools. On the other hand, closing schools does not guarantee that children will not congregate. To produce desired effects, most laws – and especially those targeting individual behavior – rely on high levels of voluntary compliance. Compliance is the important and hard part of COVID-19 policy and

research. Several elements are important to voluntary compliance:

- People are more likely to obey a law if they think the law is proper and that they have been treated fairly by the system; people who distrust government and believe the pandemic is a hoax will be less likely to voluntarily comply with social-distancing rules than those who trust the government and believe action is needed (Tyler, 1990).
- Whether or not people obey the law depends in part on the perceived attitudes of their peers and what they feel compliance says about their social identity; if wearing a mask becomes identified with one political faction, then those in other factions will regard mask-wearing as a betrayal of their own group (Kahan, 2013).
- Legal requirements might also provide social-behavioral cover, allowing businesses, for example, to require masks without having to defend the requirement on philosophical or health grounds (“sorry, I have to ask you put that mask on”) (Flay & Schure, 2013).
- Compliance has to be feasible; economic necessity may drive a worker without paid sick leave to break isolation and work when sick.

Detection of non-compliance and correction or punishment (deterrence) is most people's default theory of how law has an effect: people obey so as not to get in trouble. While voluntary compliance is the much more important driver, the visible presence of enforcement authority (like police at the borders of a locked-down community) has been a feature of the COVID-19 response and may be important to compliance locally. Perhaps more important, in a negative way, are signals from government that suggest the rules are not actually going to be enforced, which may be read as an invitation not to comply.

Figure 2.1: Potential Disparities in Risks and Benefits of COVID-19 Control Measures. Source: Authors drawing on Frohlich, K. L., & Potvin, L. (2008). Transcending the known in public health practice: the inequality paradox: the population approach and vulnerable populations. *Am J Public Health*, 98(2), 216-221.



Finally, it is useful to keep in mind how population-level interventions can reduce overall risk but leave disparities untouched or even worse. Figure 2.1 illustrates an intervention that reduces overall infection rates but substantially increase disparities: those at highest risk – say, low-wage essential workers unable to maintain physical distance from others – were already at high risk; a stay-at-home order does not change their risk, and but may benefit better off, low-risk people who can comfortably stay at home, deepening overall social inequity in disease.

The First Layer of Evidence: Temporal Association of Law and Pandemic Trends

We now have more than six month’s global experience with COVID-19 control. The legal responses have been tracked by many researchers and organizations in great detail (links to the main tracking sites can be found on the “COVID-19 Legal Research Resources” page at LawAtlas.org.) Properly done, this research is not only informative but also provides the legal data necessary for research to assess legal implementation and effects.

Legal mapping of changes in law over time has been linked with epidemiologic data to depict the association in time of control measures and pandemic features like new cases, prevalence rates, testing and mortality. In the United States, the high-level story is straightforward: the adoption of state physical distancing measures has been temporally associated with flattening of infection rates, especially when measures were deployed earlier and longer. This observation is consistent with events in other countries, and makes sense in theory: the mechanism of effect – fewer people congregating together leads to fewer infections – is obviously plausible. Also, voluntary compliance appears to have been very high in most places, which in turn fits with the high levels of support for physical distancing measures reported in polls (Lazer et al., 2020). We can sensibly assume that strict physical distancing has “worked.”

Unfortunately, this kind of high-level analysis tells us a lot less than one might think. The state-by-state association of pandemic trends with physical distancing measures is actually quite varied, as are the specific measures that people lump into the broad “physical distancing” category. Given the huge social and individual costs of the most stringent approaches, knowing that largely shutting down normal social and economic life “works” in changing pandemic trends does not address urgent questions about the relative impact of discrete social distancing elements (school and business closures, stay at home, gathering bans) let alone whether less restrictive combinations or variants might be also be associated with the same or even better results. In fact, these correlational analyses do not even tell us whether law was necessary at all, because we cannot assume that clear behavioral recommendations combined with some level of social responsibility and fear of the virus might not have produced sufficient behavior change to flatten the curve without legally established rules. This seems to have happened in Japan.

Differences in baseline infrastructure and pandemic conditions also confound observed associations. The traditional strategy for infectious disease control is a three-legged stool: (1) identify

infection with testing, (2) assess exposure with contact tracing, and (3) prevent known or reasonably infectious individuals from congregating. In the United States, the stool broke immediately because of a fiasco with test development. It is unclear whether the contact tracing leg could have withstood demand given long-term declines in public health funding. In other nations where testing and contact tracing infrastructure was robust, the virus has been contained with fewer population-based distancing rules, and similarly sturdy three-legged stools have been observed in places successfully emerging from lockdowns. Broad-based stay-at-home and closure laws sometimes emerge as aggressive prevention and other times as frantic last resorts in the face of severe control measures.

“Big picture” conclusions from overlaying law onto disease trends can be helpful – and are practically inevitable. Although data are imperfect, striking racial disparities in infection are now incontrovertible, as shown in Figure 2.2, and point to the importance of longstanding social, and not merely biological, mechanisms of vulnerability. Sharpening responses so that we are using scalpels and not butter knives requires research that deploys designs and analytic methods to produce evidence of the causal impact of specific measures or combinations of measures. We turn to that evidence next.

The Second Layer of Evidence: Observational and Simulation Research

A huge demand for answers to very difficult questions on a very short timeline is a considerable challenge to social science. The work so far takes two principal forms: studies looking at events in just one or a few places over a short time frame (observational studies) and studies that mix observed data with educated guessing and assumed processes to ask “what if?” questions (simulation studies). Randomized-controlled trials, the “gold standard” in clinical research, are rare in legal epidemiology, because the scientists cannot choose (randomly assign) who is exposed to a law and who is not.

Observational studies can use a variety of design elements and analytic strategies to credibly isolate causes and effects. The practical gold standard in legal epidemiology is the “natural experiment” where researchers take advantage of similar legal measures being implemented at different times in different places. Natural experiments can support confident inferences of causation because they allow scientists to compare “treated” and “untreated” populations on multiple dimensions, and to use a variety of sophisticated analytic strategies to test whether outcomes are consistent with hypothesized causal processes.

Both observational and simulation studies use modeling techniques that have aptly been called “wrong but useful” (Holmdahl & Buckee, 2020). As the authors explain, “[f]orecasting models are often statistical in nature, fitting a line or curve to data and extrapolating from there – like seeing a pattern in a sequence of numbers and guessing the next number, without incorporating the process that produces the pattern.” Mechanistic models, the other broad type in play during COVID-19, “forecast or simulate future transmission scenarios under various assumptions about

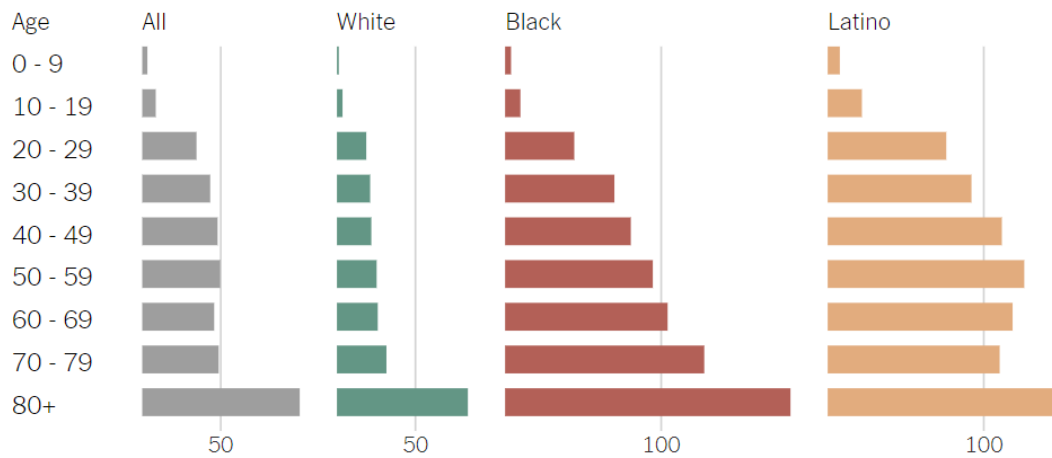


Figure 2.2: Coronavirus Cases Per 10,000 People, by Age and Race. Source: New York Times analysis of CDC data, <https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.html>

parameters governing transmission, disease, and immunity.” These models build in feedback loops and allow researchers to test the effects of alternative assumptions about what measures are used and how effective various response components will be. Simulations are both more useful than purely statistical models in providing guidance about the future effects of policy decisions, and more likely to be wrong. With those limits in mind, we proceed to further insights from research.

Timing Matters: Early Action When Prevalence Is Low Can Prevent Severe Outbreaks

Research seems to confirm intuition that earlier adoption of control measures delays or even prevents larger spikes in transmission (Nussbaumer-Streit et al., 2020). According to one modeling study, China would have reduced cases by 66%, 86% and 95% had it instituted travel restrictions, contact tracing, quarantine and testing of some travelers 1, 2 or 3 weeks earlier (Lai et al., 2020). A similar modeling study of transmission in U.S. counties estimated substantial decreases in pre-May death rates by pushing up control measures by just one (61.6%) or two weeks (55%) (Pei et al., 2020). Neither study has yet completed peer review. These models are consistent with what has been observed in several other early-reacting countries like Vietnam, which totally suppressed the virus so far through aggressive control measures including travel restrictions, quarantine and school closures in January (Ha et al., 2020).

Traditional Control Measures Can Work If Properly Executed

As we write, the impact of large-scale systematic or mandatory testing, tracing, quarantine of the exposed, and isolation of the infected has not been intensively studied for COVID-19. While we have “case studies” of countries that have successfully used one or more variants of these methods, including news stories about places like Korea and Germany, and published research (Ha et al., 2020; Ng et al., 2020) including a Cochrane review of both COVID and non-COVID quarantine studies (Nussbaumer-Streit et al., 2020), the quality of evidence is low. The same applies to traditional travel

restrictions and sanitary cordons. The initial cordon sanitaire of Wuhan was found to have reduced new cases in other countries by almost 80% until mid-February (Chinazzi et al., 2020), but we have no evidence that the sort of quarantine orders imposed on travelers from abroad by the federal government or domestic travelers by some states were successfully implemented (Myers et al., 2020) or have had any impact.

A recent modeling study in the UK suggests that effectiveness of case-finding and control would depend on the back-end intensity of the response – how completely the contacts identified were quarantined and isolated even from their families. Perhaps more importantly, the study gave an estimate of the scale of action required for control – up to 41 people would have to be quarantined for every new case of infection. Overall, the simulation literature suggests that the package of traditional measures still recommended by WHO can control a COVID-19 outbreak, but the “probability of control decreases with long delays from symptom onset to isolation, fewer cases ascertained by contact tracing, and increasing transmission before symptoms” (Hellewell et al., 2020). Evidence showing that countries can build and maintain the necessary capacity remains limited.

Population-Based Physical Distancing Combining School and Business Closures, Stay-At-Home Orders and Gathering Bans Can Suppress Transmission While They Are In Effect.

Current evidence suggests that broad limitations on populations, without individualized assessment of infection or exposure, slow and sometimes suppress the spread of the virus. However, disentangling the effects of specific requirements is difficult, and some benefits are small and may be short-lived. Based on research from previous epidemics and a few non-peer-reviewed modelling studies for COVID-19, a literature review concluded that school closures probably reduce transmission and death by small amounts. As the authors note, however, limited research does not account for secondary effects of closures on parents (Viner et al., 2020).

Laws requiring people to stay-at-home and closing businesses appear to have had substantially larger benefits. One study in the United Kingdom found that daily contacts with other people shrank from 10.7 to 2.8 after the adoption of a stay-at-home law, which the researchers relied upon in accurately forecasting significant decrease in transmissions in the following month (Jarvis et al., 2020). Another team estimated that without these laws transmission rates in the United States would have been 10 to 35 times greater (Courtemanche et al., 2020). The current resurgence of cases after the removal of these requirements is consistent with the evidence, but differences among states and regions point to the important effect of voluntary behavior change in the population.

Large-Scale Public Mask Wearing

There is not yet a high-quality body of evidence showing that mask-wearing significantly reduces transmission of respiratory diseases like flu and COVID-19 (Lyu & Wehby, 2020). It is also clear that in many places, some people wear masks without being required to do so and others resist mask-wearing even under considerable coercion. However, a new study exploring the relationship between cases and variation in state mask-wearing mandates found that mandates substantially reduced transmission accounting for as many as 450,000 fewer cases possibly in April and May (Lyu & Wehby, 2020). The research on mask-wearing mandates reflects the turbulent and unsettled science of the moment, as public health officials and experts are learning by doing.

Legal Measures to Control COVID-19 Have Not Prevented and May Have Contributed to Significant Racial Disparities in US Infections

Explaining documented disparities in COVID-19 infection and death is an important public health priority, though observed and hypothesized mechanisms are hardly surprising. Analysis of phone data in New York illustrates how poor neighborhoods with more people of color are less likely to shelter in place during the day, probably because they must work (Coven & Gupta, 2020). Emerging research also reinforces the disparate effects of the criminal justice system (Reinhart & Chen, 2020).

Conclusions

Drawing inferences about how best to control COVID-19 from layering epidemiological data and legal interventions is like studying flight by kite-flying. We can learn some basic lessons, but we will not be getting to the moon anytime soon. Adding in early observational and simulation studies gets us to the level of aeronautical engineering, which is better – but not the rocket science we need to guide response in a hugely complicated global social and economic ecosystem. Because decisions must be made, we do the best we can, but given the limits of confidence in our observations and our conclusions, “truth” has to be treated with skepticism. Findings or assumptions that don’t fit with theory should be considered suspect until better evidence emerges. Our “recommendations” are subject to all the limitations described in this Chapter, and should be regarded as educated guesses based on reasoning and best available evidence. 🌞

Recommendations for Action

Federal government:

- The federal government should support essential policy experimentation by minimizing preemption or other interference with reasonable local control measures.
- The federal government should make infection and mortality data widely available to researchers, which includes expanding the infrastructure for testing as well as the mechanisms for compiling and disseminating resulting data.
- Congress and the White House should jointly convene an independent commission or National Academies committee to examine the causes of racial and ethnic disparities in COVID-19 infections and associated harms.

State governments:

- State governments should support essential policy experimentation by minimizing preemption or other interference with reasonable local control measures.
- States should continue to promote physical distancing.
- States should strengthen capacity to implement basic public health control methods (“test and trace”).
- States should avoid travel-related restrictions, which are not supported by evidence but almost surely have large costs and harms.
- States should require mask wearing and social distancing where strict physical distancing restrictions are relaxed. Mask wearing in settings where physical distance cannot be maintained, and voluntary reduction of social contacts, would be sensible for everyone to maintain for the foreseeable future.
- States should actively address racial disparities. Racial disparities in COVID-19’s toll are striking, and so probably are disparities related to socio-economic status. If this is to change, population measures to increase physical distance have to be complemented by risk reduction measures to support people who are required by their jobs or economic necessity to work, travel on public transportation, and spend time in congregate settings. These may include provision of high-quality PPE appropriate to the physical situation, hazard pay, paid sick leave, health insurance, and redesign of work procedures and settings.

Researchers:

- Researchers should anticipate and start working to understand vaccine hesitancy.
- Researchers should develop and enforce a typology of legal interventions to ensure that research can be accurately and efficiently synthesized.
- Researchers should adopt a code of pandemic publication ethics, which aims to preserve and enhance the credibility of researchers as source of rigorous science created in good faith.
- Researchers conducting simulation studies should provide a date for their simulated outcome, and they or other researchers should systematically review performance compared with reality.



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References

- Chinazzi, M., Davis, J. T., Ajelli, M., Gioannini, C., Litvinova, M., Merler, S., Pastore y Piontti, A., Mu, K., Rossi, L., Sun, K., Viboud, C., Xiong, X., Yu, H., Halloran, M. E., Longini Jr., I. M., & Vespignani, A. (2020). The Effect of Travel Restrictions on the Spread of the 2019 Novel Coronavirus (COVID-19) Outbreak. *Science*, 386(6489), 395-400.
- Courtemanche, C., Garuccio, J., Le, A., Pinkston, J., & Yelowitz, A. (2020). Strong Social Distancing Measures In The United States Reduced The COVID-19 Growth Rate. *Health Affairs*, 39(7), 1237-1246.
- Coven, J., & Gupta, A. (2020). Disparities In Mobility Responses to COVID-19. Retrieved July 30, 2020, from <https://static1.squarespace.com/static/56086d00e4b0fb7874bc2d42/t/5ebf201183c6f016ca3abd91/1589583893816/DemographicCovid.pdf>
- Flay, B. R., & Schure, M. B. (2013). The Theory of Triadic Influence. In A. Wagenaar & S. Burris (Eds.), *Public Health Law Research: Theory and Methods* (pp. 169-192). San Francisco: John Wiley & Sons.
- Ha, B. T. T., Ngoc Quang, L., Mirzoev, T., Tai, N. T., Thai, P. O., & Dinh, P. C. (2020). Combating the COVID-19 Epidemic: Experiences from Vietnam. *Int J Environ Res Public Health*, 17(9), 3125.
- Hellewell, J., Abbott, S., Gimma, A., Bosse, N. I., Jarvis, C. I., Russell, T. W., Munday, J. D., Kucharski, A. J., Edmunds, W. J., Funk, S., & Eggo, R. M. (2020). Feasibility of Controlling COVID-19 Outbreaks by Isolation of Cases and Contacts. *Lancet Glob Health*, 8(4), e488-e496.
- Holmdahl, I., & Buckee, C. (2020). Wrong but Useful – What Covid-19 Epidemiologic Models Can and Cannot Tell Us. *New England Journal of Medicine*, 383(4), 303-305.
- Jarvis, C. I., Van Zandvoort, K., Gimma, A., Prem, K., CMMID COVID-19 Working Group, Klepac, P., Rubin, G. J., & Edmunds, W. J. (2020). Quantifying the Impact of Physical Distance Measures on the Transmission of COVID-19 in the UK. *BMC Medicine*, 18(1), 124.
- Kahan, D. (2013). Ideology, Motivated Reasoning, and Cognitive Reflection. *Judgement and Decision Making*, 8(4), 407-424.
- Lai, S., Ruktanonchai, N. W., Zhou, L., Prosper, O., Luo, W., Floyd, J. R., Wesolowski, A., Santillana, M., Zhang, C., Du, X., Yu, H., & Tatem, A. J. (2020). Effect of Non-Pharmaceutical Interventions to Contain COVID-19 in China. *Nature*.
- Lazer, D., Baum, M. A., Ognyanova, K., & Volpe, J. D. (2020). The State of the Nation: A Fifty-State COVID-19 Survey. Retrieved July 30, 2020, from <https://covidstates.net/COVID19%20CONSORTIUM%20REPORT%20April%202020.pdf>
- Lyu, W., & Wehby, G. L. (2020). Community Use Of Face Masks And COVID-19: Evidence From A Natural Experiment Of State Mandates In The US. *Health Affairs*, 39(8), 1-7.
- Myers, J. F., Snyder, R. E., Porse, C. C., Teclé, S., Lowenthal, P., Danforth, M. E., Powers, E., Kamali, A., Jain, S., Fritz, C. L., Chai, S. J., Traveler Monitoring Team. (2020). Identification and Monitoring of International Travelers During the Initial Phase of an Outbreak of COVID-19 – California, February 3–March 17, 2020. *MMWR Morb Mortal Wkly Rep.*, 69(19), 599-602.
- Ng, Y., Li, Z., Chua, Y. X., Chaw, W. L., Zhao, Z., Er, B., Pung, R., Chiew, C. J., Lye, D. C., Heng, D., Lee, V. J. (2020). Evaluation of the Effectiveness of Surveillance and Containment Measures for the First 100 Patients with COVID-19 in Singapore - January 2-February 29, 2020. *MMWR Morb Mortal Wkly Rep*, 69(11), 307-311.
- Nussbaumer-Streit, B., Mayr, V., Dobrescu, A., Chapman, A., Persad, E., Klerings, I., Wagner, G., Sibert, U., Christof, C., Zachariah, C., & Gartlehner, G. (2020). Quarantine Alone or in Combination with Other Public Health Measures to Control COVID-19: A Rapid Review. *Cochrane Database of Systematic Reviews*, 4(4), 1-47.

Pei, S., Kandula, S., & Shaman, J. (2020). Differential Effects of Intervention Timing on COVID-19 Spread in the United States. *medRxiv*, (forthcoming.)

Reinhart, E., & Chen, D. (2020). Incarceration And Its Disseminations: COVID-19 Pandemic Lessons From Chicago's Cook County Jail. *Health Affairs*, 39(8), 1-7.

Tyler, T. R. (1990). *Why People Obey the Law*. New Haven, CT: Yale University Press.

Viner, R. M., Russell, S. J., Croker, H., Packer, J., Ward, J., Stansfield, C., Mytton, O., Bonell, C., & Booy, R. (2020). School Closure and Management Practices During Coronavirus Outbreaks Including COVID-19: a Rapid Systematic Review. *Lancet Child Adolesc Health*, 4(5), 397-404.

Contact Tracing, Intrastate and Interstate Quarantine, and Isolation

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SUMMARY. Contact tracing, quarantine, and isolation are core communicable disease control measures used by public health departments as part of a comprehensive case ascertainment and management strategy. These are practices with historic roots enabled by state laws and policies and have been used by other countries to slow and stop the spread of COVID-19. To date, their implementation as part of U.S. response efforts at the national, state, and local levels has been confounded by the scale of the COVID-19 outbreak; lack of a systemic infectious disease response; insufficient and fragmented funding streams; low levels of public accountability; and concerns about the impact of such efforts on individual privacy, liberty, and travel rights, as well as the financial and personal costs that may arise out of a positive diagnosis. Recommendations have been offered by expert groups on both the scaling up of contact tracing and ensuring ethical implementation of such measures. One state has passed legislation establishing an oversight framework for state contact tracing and associated data collection and use. Legal challenges to interstate quarantine rules have, thus far, been unsuccessful. Recommendations include: appropriating federal funding adequate to mount and sustain rapid, comprehensive, culturally-appropriate state and local testing, treatment, contact tracing, and supported quarantine and isolation service efforts; building contact tracing systems that cover social as well as health care supports for those affected; and, to bolster trust and participation in public health efforts, implementing contact tracing-related health communication efforts targeted to reach the diverse array of communities affected by the pandemic.

Introduction

Testing, contact tracing, quarantine of those deemed to have come in close contact with infected people, and isolation of those who test positive, comprise a systemic response to slow the transmission of an infectious disease like COVID-19, for which there are neither effective, widely-available treatments nor a vaccine. The history of effective use of state and local contact tracing and quarantine and isolation measures to address infectious disease outbreaks date back to before the establishment of the United States. While grounded in fundamental police power authority, such efforts are subject to judicial scrutiny, as they infringe upon fundamental, constitutionally protected rights including privacy, freedom of travel, equal protection, and due process. These measures have been used in past, more limited infectious disease outbreaks with some success; however, the nature and spread of COVID-19 – and the costs of creating, implementing, and sustaining a disease control and social support infrastructure that is effective, just, and grounded in equity – are daunting.

Contact Tracing

Case investigation and contact tracing are “fundamental activities that involve working with a patient (symptomatic and asymptomatic) who has been diagnosed with an infectious disease to identify and provide support to people (contacts) who may have been infected through exposure to the patient” (CDC, 2020a). This process has been used successfully in numerous infection control programs, including tuberculosis, HIV and other sexually transmitted infections, measles, SARS, and Ebola. This type of “shoe-leather epidemiology” by “disease detectives” is key to surveillance efforts aimed at understanding the spread of the infectious disease. The authority to conduct such contact tracing efforts is rooted in the state’s core public health power to prevent and respond to infectious disease outbreaks.

Contact tracing helps slow the spread of an infectious disease in a community through the following process:

1. A trained member of a contact tracing program (“contact tracer”) gets in touch with individuals newly diagnosed with a

SARS-CoV-2 infection and/or COVID-19, educates them about the disease, and requests that they stop interacting with others during their period of infectiousness;

2. Through interviewing the infected person, the contact tracer seeks to identify recent circumstances where the infected person likely came in close contact with others and potentially exposed those people to infection;
3. The contact tracer then communicates with these “close contacts;” informs them that they likely have been exposed to the infection; and encourages them to seek out testing and to stop interacting with others until either they receive test results indicating they are not infected, or until the period of infectiousness has ended. Current Centers for Disease Control and Prevention (CDC) recommendations for most cases with mild to moderate COVID-19 symptoms are to maintain isolation and precautions until 10 days after symptom onset and 24 hours after fever has subsided without the aid of medications.

In addition, contact tracers work to connect those they contact with health care, social services and other resources that may help the contacted person to overcome obstacles to testing, treatment, and completion of their period of quarantine or isolation.

Contact tracing is a labor- and time-intensive process demanding both technical training and interpersonal skill. Like most public health interventions, agencies conducting contact tracing generally seek voluntary participation from those with new diagnoses and close contacts (“self-quarantine”), as such an approach represents the “least intrusive” means to gather personal information and maintains trust in the public health effort. As with other surveillance-related information gathered by public health departments, the identity of the person with the positive diagnosis is protected as confidential, as is information gathered during the contact tracing process.

When case counts in a particular geographic area are low, contact tracing efforts can help suppress the spread of the disease. Contact tracing also serves as a part of mitigation strategies. By identifying contacts of those identified as carrying the virus, and helping those identified contacts to get tested and to quarantine, the contact tracing process can help reduce community transmission and spread, keeping symptomatic case counts down to a level within local health care capacity. Furthermore, such efforts do not need perfect execution (identifying every symptomatic patient and every contact of every patient) to have a significant impact. Nor should contact tracing be abandoned during times of widespread virus transmission. Under such circumstances, contact tracing can be highly effective if such efforts are focused on “cluster breaking,” identifying circumstances where virus transmission occurred *en masse*, such as in large gatherings, nursing homes, processing plants, dormitories, cruise ships, and jails and prisons.

The effectiveness and efficiency of contact tracing will be affected by the characteristics of the infection, the availability of timely testing, as well as the contact tracing agency’s capacity to handle the area case volume. Each positive diagnosis may result in

numerous close contacts that may then require rapid follow up (CDC, 2020). Because SARS-CoV-2 spreads easily and asymptotically, COVID-19-related contact tracing must occur extremely rapidly, or risk becoming ineffective. This presents significant implementation challenges for most state and local health departments, which have suffered devastating budget and personnel cuts over the past 15 years, including the elimination of 50,000 public health positions in the 2008 recession alone (Watson et al., 2020). The Johns Hopkins Center for Health Security estimates that an effective response to the national spread of COVID-19 will require adding approximately 100,000 contact tracers to the existing public health workforce (Watson et al., 2020). Because of the lack of effective treatments and vaccines, if contact tracing efforts are ineffective or overwhelmed, communities nationwide risk nearly unchecked spread of COVID-19, and disease control will require the implementation of broader, more blunt public health measures, such as the introduction of community stay-at-home measures and business and school closures.

Contact tracing is more than a surveillance and infectious disease control mechanism. The scale up of the contract tracing workforce can result in the hiring of many workers who may have lost other means of support during the pandemic. When contact tracing programs are rooted in values such as human rights and dignity, due process, and community engagement, those hired as contact tracers will be drawn from, reflect the cultures within, and speak the languages of, the local communities they will serve.

To build public health literacy and trust in the public health response efforts, when implementing contact tracing initiatives, public officials and public health agencies should supplement the frontline disease management efforts with targeted public education campaigns about the processes that will be used in local contact tracing efforts, the need for public cooperation with such efforts, and how this collaboration will aid COVID-19 response.

As the CDC notes, contact tracing also is “part of the process of supporting patients with suspected or confirmed infection.” Such efforts, ideally, will provide those with new diagnoses and their close contacts with information about available local social and health services, facilitating rapid access to care and easing burdens related to quarantine and isolation. This may include basics, such as food, laundry, housing assistance (or hotel-based services for those without stable housing); childcare or dependent care services; connection with health insurance and/or treatment services; and income supports, ways to get protected time off, or unemployment assistance (CDCb, 2020). Tracing efforts also should include follow up and check in with cases and contacts periodically during their time in self-quarantine, assessing how well the contact is coping, and reminding the service recipients to continue to self-monitor while staying at home. These steps not only advance justice, equity, and health literacy, but will also help build and maintain public trust in public health efforts, improve adherence with public health directives, and ensure that social and health services are provided in a community- and culturally-appropriate manner.

Legal Issues with Contact Tracing Implementation by State and Local Health Departments

There are few legal barriers to local implementation of COVID-19 contact tracing efforts. State legislatures long ago delegated to public health agencies the authority and responsibility for infectious disease surveillance, investigation, and control. Furthermore, contact tracing is viewed by the public health community as a sound public health practice. Finally, state emergency powers laws have given state executives and their associated agencies broader authority to purchase resources and services to respond to the epidemic.

Both implementation and legal issues have arisen related to contact tracing during the COVID-19 pandemic. The nation's slow response and lack of testing meant that COVID-19 rapidly became widespread. This led state and local health departments to redeploy their scant supply of extant contact tracers from other surveillance duties to COVID-19-related efforts. That capacity was then overwhelmed, leading the federal government, as well as state and local health departments, to begin hiring, training, and deploying additional contact tracers, or contracting with outside companies and agencies to provide area contact tracing services.

Many states and communities also have chosen to rely on engaging with close contacts via telephone call centers, rather than through face-to-face interviews. While this may reduce outreach-related time and travel costs, and increase the safety of contact tracers, such an approach could adversely affect public trust and participation in contact tracing efforts, as contact tracers will be more anonymous (and may be mistaken for telemarketers). Best practice standards recommend that, to maximize trust, those hired as contact tracers come from the communities they will serve. This may not always occur with tracing operations that are centralized (as opposed to run by the local public health department) or that use a national pool of employees. Furthermore, the size and scale of the outbreak have led to recommendations that human contact tracing efforts be supplemented with digital contact tracing applications.

The lack of adequate federal funding to support a massive scale up in contact tracing capacity means that most jurisdictions struggle to use contact tracing as a means to suppress the outbreak. Furthermore, at this time, few jurisdictions share information publicly about the effectiveness of their contact tracing efforts, raising questions of accountability and, for those contracting with external vendors, the transparency of the use of public funds.

Both the use of contractors to conduct contact tracing efforts and potential digital contact tracing applications have raised significant privacy and data use questions (see Chapter 5). In June 2020, Kansas passed the COVID-19 Contact Tracing Privacy Act during an emergency session of the legislature (Kansas Legislature, 2020). Several provisions make explicit best practices for contact tracing, including establishing expectations for hiring qualified contact tracers, as well as privacy protections over information collected and handled during the contact tracing process. Other provisions significantly favor individual privacy over benefits the use of that private information might offer to public health efforts. The law prohibits the use of cellphone location data for contact tracing purposes. It also establishes that third

parties may not “be required to collect or maintain data regarding infected persons or contacts for the purpose of contact tracing,” thereby prohibiting public health agencies from requiring that places such as businesses and schools track the COVID-19 status of their employees or students, respectively (Kansas Legislature, 2020). Finally, the law also establishes that participation in contact tracing is voluntary, and that neither contacts nor those with new diagnoses may be compelled to participate in the contact tracing process. It is unclear whether these provisions will foster greater public trust and participation in contact tracing efforts or reduce any stigma that may be associated with a positive COVID-19 diagnosis. Alternatively, it is also unclear whether, by raising these as concerns, the Kansas law may foment increased skepticism and reluctance to collaborate with public health.

Most public health experts and ethical guidance recommend that participation in contact tracing efforts remain voluntary (CDC, 2020b). However, in June 2020, officials in Rockland County, NY, in an effort to compel the participation in contact tracing efforts of several people suspected of having come in contact with the new coronavirus during gatherings held in violation of local social distancing rules, issued subpoenas against eight people believed to have attended one of the gatherings, threatening the individuals with \$2,000/day fines for noncompliance (Shanahan, 2020). While the measure succeeded in garnering contact participation, establishing such an approach as a widespread policy is not recommended, as it not only raises significant implementation questions, including concerns about inequitable application, but it also risks public trust in and acceptance of current and future infectious disease control efforts.

Quarantine and Isolation

When medical treatment and prevention measures are inadequate or unavailable, public health efforts may need to more heavily rely upon older forms of public health intervention to stem the spread of dangerous infectious diseases. Quarantine is the restriction of movement of an individual suspected of having been exposed to an infectious disease. Isolation is the restriction of movement of an individual who has a confirmed case of an infectious disease. (Other restrictions on mass movement such as stay-at-home orders are addressed in Chapter 4). The history of laws and cases supporting the state and community exercise of what came to be known as their “police power authority” to protect the public from communicable diseases via quarantine and isolation trace back to the earliest days of the United States (Parmet, 2020). As stated by Justice Harlan in the 1905 Supreme Court case of *Jacobson v. Massachusetts*, the Court “has distinctly recognized the authority of a State to enact quarantine laws.”

However, this power is neither unbounded nor exempt from judicial review, even in times of emergency. The use of these response strategies continues to “raise vital social, political and constitutional questions because they interfere with basic human freedoms: association, travel, and liberty” (Gostin & Wiley, 2016).

As noted in the Contact Tracing Section above, ethical best practices for public health recommend that the “least restrictive” approach be used to bring about the desired public health outcome. Quarantine and isolation are meant, first and foremost,

as preventive, not punitive measures (Gostin & Wiley, 2016). The state or community should be prepared to demonstrate that quarantine and/or isolation is necessary, and not merely “erring on the side of caution” or a tactic to assuage public fear. Ethical quarantine and isolation practices also means:

- Use of such measures should be based on the best available science concerning the risk and communicability of the disease;
- Science should also inform the targeting of the intervention, as well as the effectiveness of the proposed control measure;
- Whenever possible, voluntary self-quarantine and home-based efforts should be pursued and determined to have failed to achieve the public health goal prior to enacting compulsory measures;
- Such interventions should be as narrowly applied as possible and implemented with consideration for due process rights;
- These measures should be conducted safely and humanely; and
- Ideally, those who must be quarantined and isolated will be supported during their period of restriction, not only with basic needs such as health care, food, and sanitary conditions (Parmet & Sinha, 2020), but also housing (if homeless), eviction protection, other social resources, and employment protection (Allen et al., 2020).

Isolation and quarantine decisions are generally reviewable in court, under a writ of habeas corpus. While courts often defer to state disease control decisions, courts have overturned quarantine measures for being ineffective under the circumstances, improperly implemented under a local emergency powers ordinance, and/or motivated by discriminatory intent (Parmet & Sinha, 2020).

Novel legal questions have not been raised about health departments applying “traditional” quarantine and/or isolation measures to individuals during the COVID-19 epidemic (e.g., contacts discovered through tracing efforts or newly diagnosed cases). In fact, the scale of the COVID-19 epidemic, coupled with public health workforce shortages, has made challenging, if not unfeasible, the close monitoring of those advised to quarantine.

One type of quarantine — travelers’ quarantine — has been the focus of significant legislative activity, commentator scrutiny, and judicial review during the COVID-19 pandemic. From early March until early July 2020, at least 28 states, the city of Chicago, and Puerto Rico have passed rules imposing quarantine on travelers into their jurisdictions from other places where disease is more widespread (Tolbert et al., 2020). Judicial review of challenges to the structure and enforcement of state laws imposing traveler quarantines has occurred in at least two federal district courts.

From a public health perspective, interstate traveler quarantines are, at best, a blunt instrument for controlling the spread of COVID-19, especially in light of the lack of effective, timely, widespread testing; the amount of asymptomatic and low-symptom transmission; and the logistics of tracking interstate travel. If anything, such rules may be as much a health communication

strategy to encourage out of state people to stay home as a measure to control local disease transmission.

However, in actions brought before federal district courts in Maine and Hawai‘i, judges declined to disturb state rules requiring 14-day quarantines for visitors and local residents traveling into their jurisdiction from out of state (*Bayley’s Campground v. Mills*, 2020; *Carmichael v. Ige*, 2020). In *Bayley’s Campground*, the judge acknowledged the freedom to travel’s roots in several core constitutional sources, including the Privileges and Immunities, Commerce, Due Process, and Equal Protection Clauses, and felt the quarantine measure should be subject to strict scrutiny, rather than the *Jacobson* case’s more contextual “rule of reasonableness” (Parmet, 2020). Nevertheless, the judge found the state had a compelling interest in protecting the public from many infectious people coming into the state and potentially overwhelming their local health system capacity, and that current limits on testing, and our limited knowledge of COVID-19 virus immunity, meant there were no more feasible, less restrictive approaches the government could take under the circumstances (*Bayley’s Campground v. Mills*, 2020).

In *Carmichael*, instead of selecting either the *Jacobson*-style review or the more modern strict scrutiny review to assess Hawai‘i’s rule requiring visitors and returning residents undergo 14-day quarantines upon return, the judge ran the case through both approaches, and found that the state’s rationale and approach would pass muster under either standard.

Absent building strong, equitable, trustworthy, and reliable local testing and communicable disease case ascertainment and management systems across the United States, the country risks devastating, uncontrolled COVID-19-fueled morbidity, mortality, and economic disruptions until safe, effective, and widely-accessible treatments and vaccines become available. With improvement of our testing and tracing capacity and understanding of COVID-19, it will be more feasible for states and communities to implement more targeted control measures. At that time, courts scrutinizing state actions would be justified in raising its expectations for narrower, individually-tailored, rather than population-focused, interventions. 🦠

Recommendations for Action

Federal government:

- Congress should appropriate significant, expanded, ongoing funding (until the abatement of the pandemic or widespread uptake of a safe, effective COVID-19 vaccine) for state and local testing and contact tracing efforts; appropriations should require the employment of a culturally-sensitive, linguistically-competent workforce reflecting the make-up of the community.
- Congress should strengthen, extend for a longer period of time, and minimize employer exemptions from the protected time-off benefits available under the Family and Medical Leave Act and Families First Coronavirus Response Act to facilitate the needs of employees who are quarantined or isolated due to COVID-19 or have caregiver duties for those who have been quarantined/isolated.

State governments:

- State legislatures should fund, and state health departments should implement and/or contract for, robust, ongoing contact tracing systems that are closely connected to the communities they serve, including employment of a culturally-diverse and -sensitive workforce.
- State health departments should implement and/or contract for contact tracing services that, whenever possible, engage existing community-based organizations to facilitate connection with diverse local communities and service needs.
- State health departments, in their implementation of contact tracing training and programs, should seek to identify and address unique barriers and concerns that may arise with outreach and service provision efforts to immigrant and migrant populations, including issues associated with immigration and public charge rules.

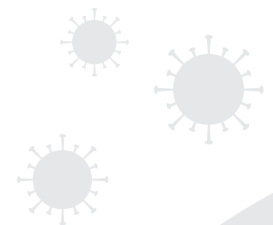
- State legislatures should fund, and state health and social services agencies should implement, systems that ensure those testing positive and identified as close contacts have access to health care, mental health care, social services, and employment and housing protections needed for effective SARS-CoV-2 treatment and quarantine.
- Governors and/or executive branch agencies overseeing state-led contact tracing programs should regularly report data to the public related to their contact tracing outreach and case ascertainment efforts; if necessary, legislatures should mandate these data disclosures.
- Governors through executive orders and/or legislatures through amending extant housing, utilities, and employment laws should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to quarantine and/or isolation.
- State health departments should develop and implement expanded, multilingual health communication efforts to boost public trust and participation in, and awareness of, contact tracing initiatives.

Local governments:

- Local government should fund, and local health departments should implement, ongoing contact tracing systems that are closely connected to the communities they serve, including employment of a culturally-diverse and -sensitive workforce.
- Local health departments should implement and/or contract for contact tracing services that, whenever possible, engage existing community-based organizations to facilitate connection with diverse local communities and service needs.
- Local health departments, in their implementation of contact tracing

training and programs, should seek to identify and address unique barriers and concerns that may arise with outreach and service provision efforts to local immigrant and migrant populations, including issues associated with immigration and public charge rules.

- Local health departments overseeing state-led contact tracing programs should regularly report data related to their contact tracing outreach and case ascertainment efforts.
- Local government, through emergency orders and/or amending extant housing, utilities, and employment ordinances, should extend protections against eviction, mortgage foreclosure, and utility shut off connected with quarantine and/or isolation.
- Local government and health departments should develop and implement expanded, multilingual health communication efforts to boost public trust and participation in, and awareness of, contact tracing initiatives.



About the Author

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References

- Allen, D., Block, S., Cohen, J., Eckersley, P., Eifler, M., Gostin, L., Goux, D., Gruener, D., Hart, V., Hitzig, Z., Krein, J., Langford, J., Nordhaus, T., Rosenthal, M., Sethi, R., Siddarth, D., Simons, J., Sitaraman, G., Slaughter, A., Stanger, A., Tabarrok, A., Tretikov, L. A., & Weyl, E. G. (2020). Roadmap to Pandemic Resilience. Retrieved July 24, 2020 from Harvard University Edmond J. Safra Center for Ethics, https://ethics.harvard.edu/files/center-for-ethics/files/roadmaptopandemicresilience_updated_4.20.20.pdf
- Bayley's Campground Inc. v. Mills, No. 2:20-cv-00176-LEW (D. Me. May 29, 2020)(denying preliminary injunction). Retrieved July 24, 2020, from <https://www.clearinghouse.net/chDocs/public/PR-ME-0001-0004.pdf>
- Carmichael v. Ige, No. 1:20-cv-00273-JAO-WRP (D. Haw. July 2, 2020)(denying request for temporary restraining order). Retrieved July 24, 2020, from https://www.scribd.com/document/467893695/20200703-WEB-Judge-s-Order#from_embed
- Centers for Disease Control and Prevention (CDC)(2020a). Interim Guidance on Developing a COVID-19 Case Investigation & Contact Tracing Plan: Overview. Retrieved July 31, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/php/contact-tracing/contact-tracing-plan/overview.html>
- Centers for Disease Control and Prevention (CDC)(2020b). Case Investigation and Contact Tracing: Part of a Multipronged Approach to Fight the COVID-19 Pandemic. Retrieved July 31, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/php/principles-contact-tracing.html>
- Gostin, L. O., & Wiley, L. F. (2016). Public Health Law: Power, Duty, Restraint (3d. ed.). Oakland, CA: University of California Press.
- Kansas Legislature (2020). Supplemental Note on House Bill No. 2016, As Amended by House on Final Action. Retrieved July 31, 2020, from http://www.kslegislature.org/li_2020s/b2020s/measures/documents/supp_note_hb2016_01_0000.pdf
- Parment, W. E. (2020). Rediscovering Jacobson in the Era of COVID-19. *Boston University Law Review Online*, 100, 117-133. Retrieved July 24, 2020, from <http://www.bu.edu/bulawreview/files/2020/07/PARMET.pdf>
- Parment, W. E., & Sinha, M. S. (2020). COVID-19 — The Law and Limits of Quarantine. *New England Journal of Medicine*, 382(15), e28(1)-e28(3).
- Shanahan, E. (2020). Party Guests Wouldn't Talk After 9 Tested Positive. Then Subpoenas Came. *New York Times*. Retrieved July 23, 2020, from <https://www.nytimes.com/2020/07/01/nyregion/rockland-coronavirus-party.html>
- Tolbert, J., Hall, C., Orgera, K., Singer, N., Mengistu, S., & Tian, M. (2020). State Data and Policy Actions to Address Coronavirus. Retrieved July 24, 2020 from Kaiser Family Foundation, <https://www.kff.org/health-costs/issue-brief/state-data-and-policy-actions-to-address-coronavirus/>
- Watson, C., Cicero, A., & Blumenstock, J. (2020). A National Plan to Enable Comprehensive COVID-19 Case Finding and Contact Tracing in the US. *Johns Hopkins Center for Health Security*. Retrieved July 24, 2020, from https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200410-national-plan-to-contact-tracing.pdf

Mass Movement, Business and Property Control Measures

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SUMMARY. Government powers support the use of physical distancing measures as a strategy to mitigate the spread of COVID-19. This Chapter examines the efforts of governments to limit mass movement and large gatherings, close businesses and schools, and restrict non-essential personal, recreational, and commercial activities. Government legal authority to impose these restrictions to stop the transmission of an infectious disease such as COVID-19 is quite broad, and these measures are essential tools to reduce the community spread of COVID-19. However, government orders that restrict movement or activity must consider the effects on constitutional rights; the economic, social, and health impacts that restrictions impose; and the potential for inequitable burdens on marginalized communities if supportive policies are not implemented along with restrictions. Movement and activity restrictions in the form of stay-at-home orders, gathering size limitations, and business and school closures have been instituted widely during the initial COVID-19 response, primarily by state governments, although local governments have also imposed these measures. Often politically controversial, numerous legal challenges have been brought against government orders restricting movement, imposing gathering limits, and closing businesses. The government has prevailed in most of these legal challenges, and this deference to government-imposed restrictions demonstrates an appropriate balancing of public health and other considerations under circumstances of scientific uncertainty. However, government officials must take affirmative steps to set up systems that render widespread restrictions on movement and activity less necessary to contain COVID-19 and to ensure that when restrictions and closures are in place that supportive policies mitigate disparate burdens on marginalized communities.

Introduction

This Chapter explores the many actions taken by federal, state, and local governments to contain the spread of COVID-19 through restrictions on mass movement; control of personal interactions and property uses; and limitations on personal, recreational, educational, and commercial activities. Most pandemic plans consider physical separation of people an essential strategy to stop the spread of an infectious disease—like COVID-19—for which there is no effective vaccine or treatment. Among the available options for reducing disease transmission are bans on gatherings; stay-at-home orders, travel restrictions, and other restrictions on mass movements; and closures of businesses, schools, and other institutions.

Federal powers to control interstate commerce are broad enough to restrict travel between states or into the country to stop the spread of an infectious disease. Federal officials may also issue travel advisories as guidance and may place incoming international travelers under quarantine or isolation (see Chapter 3).

State government powers—and local government powers by extension—provide significant authority to restrict movement of individuals, limit activities, and impose property controls (Gostin & Wiley, 2020). These powers are grounded in the states' police powers, which grant the states the authority to take steps to protect the health and well-being of the population. Consequently, state powers are considerably broader in scope than federal powers in these areas. Past interpretations of state police powers by courts recognize that states can force businesses to shut down or relocate to protect health (*New York City v. New St. Marks Baths*, 1986; *The Slaughter House Cases*, 1873) and can impose restrictions or requirements on individuals to stop the spread of contagious diseases (*Jacobson v. Massachusetts*, 1905). State executives possess statutory authority under emergency response laws to impose restrictions on movement, bans on gatherings, and closure of commercial and recreational activities. These statutes grant state governors or other designated officials the authority to declare emergencies and issue executive orders tailored to reduce the spread of a contagious outbreak of a respiratory disease like COVID-19.

While these government powers are extensive, constitutional constraints—including protections for due process and equal protection, and freedom of speech, religion, and assembly—apply to government actions to respond to infectious disease outbreaks and can give rise to legal challenges to these powers. Courts typically defer to government judgment on the use of police powers during outbreaks of contagious diseases, even when there is scientific uncertainty about whether the threat posed by a new disease merits extra precaution. However, courts may invalidate government restrictions on movement, interaction, or activity that are overbroad, unsupported by scientific evidence, or applied in a discriminatory manner (*Jew Ho v. Williamson*, 1900).

Ethical best practices support imposing closures and restrictive measures on activity when such measures are reasonable, informed by scientific understandings of risk, and implemented in the least restrictive way possible to achieve the goal of mitigating the spread of infection (Gostin & Wiley, 2020). Pandemics can exacerbate already problematic racial and ethnic health disparities (CDC, 2020). When closures and movement restrictions are necessary to contain infectious disease outbreaks, it is vital that government provide legal protections and supportive resources to the people most vulnerable to negative consequences that coincide with closures and movement restrictions—often poor people of color, who disproportionately suffer from losing access to public services, paychecks, childcare, and mobility (Yearby & Mohapatra, 2020). Government-provided support—including access to food, health services, income support, and employment, utility, and housing protections—allows people to comply with stay-at-home orders. These programs promote equity and protect people—especially those living in poor and marginalized communities—from the negative economic, social, and health consequences that occur during a pandemic.

Mass Movement, Business and Property Control Measures during COVID-19

Government Actions to Control Movement and Limit In-Person Interactions

Despite large outbreaks of COVID-19 in China and Europe in early 2020, federal and state government officials in the United States acted slowly to respond to the risks posed by the disease. It wasn't until early March 2020 that government officials began to implement steps to contain the spread of the disease, through limiting in-person interactions. Government officials imposed stay-at-home orders and travel restrictions; limited the size of, or prohibited altogether, non-essential gatherings; and closed schools and non-essential businesses.

Federal officials attempted to limit travel into the United States, imposing partial travel restrictions on travelers from a variety of countries including China, European Union members, Brazil, Canada and Mexico, while simultaneously attempting to ban most immigration (see Chapter 33). Federal agencies have limited legal power related to closures and movement restrictions within the country, but considerable influence on policies adopted by states, localities, and private actors. Agencies including the Centers for Disease Control and Prevention (CDC), Department of

Labor, and Department of Education offered voluntary COVID-19 guidance regarding decisions to limit gatherings and close—or reopen—businesses and schools. Contradictory messages from federal officials and the widespread perception that the Trump administration has altered expert agency guidance on closures to conform to political preferences has limited the widespread acceptance of this guidance, politicized closure decisions, and undermined trust in government scientific experts. In addition, President Trump issued an executive order that invoked the Defense Production Act to potentially require meatpacking facilities to remain open in lieu of state-level closures (see Chapter 23 for more information on the Defense Production Act).

As community spread of COVID-19 became evident, state and local governments acted to forestall the growing outbreak by limiting movement and in-person interactions. By mid-March 2020, every state had declared an emergency related to COVID-19, expanding the authority of state officials to act rapidly to intervene. Drawing on existing emergency powers, most states imposed a set of movement, gathering, and activity restrictions designed to require significant physical distancing to reduce the spread of the SARS-CoV-2 virus that causes COVID-19. These provisions applied an extensive and varied array of strategies, including bans on gatherings, stay-at-home orders for non-essential activities, closures of schools and businesses, and mask-wearing mandates among many other provisions (including the imposition of quarantine on travelers from other states with high case numbers – see Chapter 3). Some local governments also enacted similar restrictions, in some cases with more stringent limitations than state-level requirements, provided that states permitted local variation. Indeed, some of the most contested legal and political disputes during the initial months of the pandemic involved disagreements over the ability of local governments to impose movement restrictions and mask mandates that were stricter, or more lenient, than state requirements (see Chapter 9).

Gathering bans were among the first restrictive actions taken by many state and local governments in response to the initial COVID-19 outbreaks. Throughout March, many state and local officials imposed increasingly strict limitations on the size of non-essential group gatherings, while others merely issued guidance discouraging such gatherings. In many states, orders limiting gathering size were revised rapidly to reduce in-person interactions as the scale and dangerousness of the outbreak became more obvious. New York, for instance, imposed a ban on gatherings larger than 500 people on March 12, 2020, limited social and recreational gatherings to 50 people on March 18, 2020, and banned non-essential gatherings of any size on March 22, 2020. State gathering bans exhibited great deal of variety in terms of size limitations with many states maintaining a limit of 10 people. The definition of “essential” gatherings varied across states as well. While indoor recreational gatherings exceeding size limits—such as concerts or sporting events—were universally proscribed, states were divided over whether gatherings for religious worship constituted an essential activity, with a few states explicitly exempting religious worship services from gathering size caps.

In many states, gathering bans coincided with the imposition of widespread stay-at-home orders. Following the lead of some early-acting local jurisdictions such as Seattle/King County and San Francisco, the state of California issued the first statewide stay-at-home order on March 19, 2020. Nearly every state imposed some version of a stay-at-home order or advisory in late March or early April as COVID-19 case numbers continued to increase. Most of the stay-at-home orders required all individuals to stay home unless working in essential jobs or accessing necessities such as food, prescriptions, or emergency health care. Many states exempted outdoor activities with physical distancing from these restrictions. States exhibited variation in the language of the stay-at-home orders along a continuum of clarity. For instance, Michigan's order included clear prohibitive language ("all individuals...are ordered to stay at home or at their place of residence") while Texas's order adopted a somewhat less pointed statement ("every person...shall...minimize social gatherings and minimize in-person contact").

Most states ordered businesses and schools to be closed contemporaneously with the stay-at-home orders and gathering bans. Non-essential businesses—including most office, factory, and service sector workplaces—were forced to cease in-person operations temporarily. Essential businesses and their workers were permitted to continue operations as exceptions to these orders, allowing health care institutions (although in many states not elective or preventive health care procedures), food producers and sellers, and critical infrastructure workers including some government and delivery workers to continue to work in-person and on-site. Again, these state orders demonstrated some variety in content. Most states explicitly closed workplaces that could not operate and maintain the limits on gathering size and businesses where people have close contact for extended periods, such as dine-in restaurants, gyms, bars, salons, and theaters. State and local governments also closed schools to prevent the spread of COVID-19, although childcare for essential workers was permitted in most jurisdictions. State and local officials are currently weighing the risks of opening schools for fall 2020.

The combination of stay-at-home orders, widespread business and school closures, and limitations on in-person gathering seems to have effectively flattened the rising curve of COVID-19 infections between March and May 2020, although it's unclear from the evidence precisely which measures were effective, and if some were not (Castillo et al., 2020; Chapter 2). Nevertheless, many state and local officials that had imposed restrictions removed them, at least in part, beginning in May and June 2020. The quick removal of restrictions in many jurisdictions was prompted not by public health guidance, but rather by political pressure from President Trump and his supporters, protests organized by conservative groups, and a large number of lawsuits challenging stay-at-home orders and business closures.

Lifting restrictions on in-person interactions too quickly has been disastrous. States that removed their restrictions quickly, such as Arizona, Florida, Georgia, and Texas, have seen their COVID-19 cases again begin to increase, and some of these states have had to re-impose additional restrictions on movement and business closures throughout June and July 2020. Similarly tragic is the

failure of federal and state government officials to use the time while most people were staying at home to implement programs with sufficient capacity to test, contact trace, and isolate COVID-19 cases. Had stay-at-home orders been extended and testing/tracing capacity developed, this country would likely have been controlling a much smaller COVID-19 epidemic with targeted restrictions rather than the fluctuating application of state (and increasingly local) governments' restrictions on mass movement and business and school closures that will need to occur intermittently until an effective treatment or vaccine for COVID-19 becomes available. The rapid rollback of restrictions in many U.S. states can be contrasted unfavorably with the more successful approaches taken by most European countries, which maintained their movement restrictions and closures for longer and implemented more robust social support programs, allowing rates of COVID-19 infection to remain low when restrictions were eased.

Many states have attached legal penalties to movement, interaction, and closure restrictions that authorize fines (and less frequently arrest or imprisonment) for people found in violation of these restrictions. While legal sanctions can be justifiable to incentivize compliance with the law, the effects and incentives of enforcing physical distancing restrictions are complex. Enforcement of public health regulations may occur differentially across populations, with people of color more likely to face aggressive enforcement than white people for noncompliance. Additionally, mandatory enforcement may entrench opposition to public health interventions by inflaming political divisions in a counterproductive way. These concerns suggest that voluntary compliance with public health restrictions is preferred when feasible.

Legal Challenges to Government Restrictions

The imposition of government restrictions on gatherings, business operations, and related activities have resulted in numerous legal challenges, many of them still ongoing at the time of this writing. Litigants sought to have courts overturn government orders based on a number of different legal theories, including alleged violations of fundamental constitutional rights, due process, and equal protection. Many of the judicial rulings have relied on *Jacobson v. Massachusetts*, the 1905 U.S. Supreme Court case that upheld compulsory vaccination requirements imposed during an infectious disease outbreak as valid within state police powers, but also recognized that state power to constrain individuals was not unlimited and subject to court review. Modern courts' interpretations of *Jacobson*, however, have varied, and created disparate standards of analysis applied to constitutional challenges to government COVID-19 restrictions (Parmet, 2020; Wiley & Vladeck, 2020).

One analytical approach courts have used to evaluate state powers has been to apply deference to government interventions to protect public health while still affording consideration of applicable constitutional rights that could be violated by the state. In *South Bay United Pentecostal Church v. Newsom*, Chief Justice John Roberts voted not to block a California order limiting the size of attendance at religious worship services to 25% capacity or 100 attendees, noting in his concurring opinion both deference to public health officials who are "politically accountable" and

the order's consistency with upholding religious free exercise rights. Roberts addressed the issue of comparative restrictions between religious gatherings and comparable secular gatherings that involve large groups in close proximity for extended periods of time, finding that the secular gatherings face "similar or more restrictions" than religious gatherings. This ruling—and the subsequent Supreme Court ruling in *Calvary Chapel v. Sisolak*—seems to support the position that courts should give the government wide latitude to enact limitations on gatherings, but that the Court may step in if fundamental rights including religious free expression are impacted without sufficient justification. However, since both *South Bay* and *Calvary Chapel* denied request preliminary injunctions, the Court may ultimately take a different position on the merits.

Religious organizations have been frequent litigants seeking to overturn government restrictions that place limitations on the number of people permitted to attend religious worship services. These claims, grounded on claims that religious institutions and worshippers face unconstitutional free exercise and equal protection violations when religious gatherings are not considered essential or are subject to greater limitations than other businesses, have mostly been resolved in favor of the government, just like *South Bay* and *Calvary Chapel* cases. In several cases, however, courts have invalidated state orders that placed restrictions on religious worship that did not allow for sufficient alternatives. For example, a church in Kentucky successfully argued to overturn a state order prohibiting mass gatherings, including drive-in gatherings, which the court ordered the state to allow (*Maryville Baptist Church v. Beshear*, 2020).

Another analytical approach courts have used to evaluate state powers was demonstrated by the Fifth Circuit in *In re Abbott*. The court, in allowing a state law that suspended abortion services as not essential during the declared emergency, applied a more lenient and deferential view toward state power during an emergency, upholding state restrictions imposed due to an epidemic unless they constitute "a plain, palpable invasion of rights."

Regardless of jurisprudential interpretation, the vast majority of COVID-19 legal challenges decided so far have upheld government authority to implement movement restrictions, activity limits, and closures. For example, lawsuits brought by individual plaintiffs have argued that stay-at-home orders infringed on peaceable assembly, interstate travel, and due process rights. Most courts dealt with these challenges either by finding that emergency powers justified deference to state actions, or by finding that no fundamental rights were violated or discriminated against and state actions clearly met the rational basis standard.

Businesses alleging the government limitation on business operations violated their due process or equal protection rights also challenged state restrictions, with some plaintiffs maintaining that business closures were enacted without adequate process or hearing, or that closure orders constituted an unconstitutional taking by depriving business owners of property without just compensation. Courts rejected both of these arguments. Due process challenges failed because operating a business is not a

fundamental right and that state actions to protect public health easily met the rational basis test. Likewise, courts concluded that, even if takings claims were valid, the remedy would be damages and not an injunction against the closure order.

Specific types of businesses also challenged the definitions of "essential" used in state and local orders, alleging that such categories were either too narrowly construed or defined in such a way to create equally situated businesses differently. Again, the government succeeded in virtually all of these challenges, as courts routinely deferred to government judgments in determining which businesses were essential, including closures of factories, gyms, firearms sellers, and elective and non-emergency health care procedures. However, courts have split on the issue of whether state limits on abortion services can be upheld, with the Fifth and Eighth Circuits allowing the restrictions to stand and the Sixth, Tenth, and Eleventh Circuits enjoining enforcement of these restrictions (see Chapter 15).

A final type of legal challenge advanced the argument that state stay-at-home orders and movement and business restrictions exceed the authority of or delegation to executive branch officials promulgating these orders. Claims of this sort—brought by individuals, businesses, and legislatures—have not had much success, but the Wisconsin Supreme Court overturned statewide stay-at-home and business closure orders, finding they exceeded the statutory authority of executive branch officials (*Wisconsin Legislature v. Palm*, 2020). States should consider clarifying the scope of emergency powers to avoid these disputes in the future.

In sum, government COVID-19 orders restricting movement, imposing gathering limits, and closing businesses have mostly withstood legal challenges. Given the underlying circumstances of the pandemic and the current options available to reduce the spread of COVID-19, deference to government-imposed restrictions is appropriate. 🌐

Recommendations for Action

Federal government:

- Congress should fund and CDC should take the lead in developing a unified national approach to rapid testing, contact tracing, and isolation of people infected with SARS-CoV-2 to allow for targeted interventions for COVID-19 rather than widespread closures and limitations on physical interaction.
- Congress should appropriate significant, expanded, ongoing funding to support people who lose jobs or income due to state and local stay-at-home orders, business and school closures, and gathering restrictions and to allow them to comply with these restrictions.
- Congress should enact legislation that strengthens and extends legal protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to stay-at-home orders, business and school closures, and gathering restrictions.
- Congress should appropriate significant, expanded, ongoing funding to support small businesses and school systems that were forced to close due to closure orders.
- CDC should develop rigorous, scientifically-grounded, apolitical guidance for safe operation of schools, for safe operation of schools, business, and indoor and other settings to assist government officials in making risk assessment decisions to prevent the spread of COVID-19.

State governments:

- States legislatures should enact legislation clarifying the scope and authority of state officials to limit person-to-person interaction and impose closures, movement restrictions, gathering bans, and physical distancing requirements.
- Governors or other designated officials should promote physical distancing to reduce the spread of COVID-19 through incentives, supportive programs, and legal protections that allow compliance with distancing guidance and reduce inequitable disparate impacts of gathering restrictions and closures. If mandatory restrictions and closures are implemented, state officials should base these measures on the best available epidemiological and scientific evidence.
- Governors, through executive orders, and/or legislatures, through amending legislation should empower local governments to implement targeted and scientifically-appropriate interventions to respond to COVID-19, including the ability of local jurisdictions to impose more stringent limitations than the state on movement of individuals, gathering sizes, mask requirements, and closure of businesses, schools, and other activities.
- Governors, through executive orders, and/or legislatures, through amending extant housing, utilities, and employment laws, should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to stay-at-home orders, business and school closures, and gathering restrictions.

Local governments:

- Local ordinances should allow for the imposition of targeted and scientifically-appropriate closure, movement, and physical distancing restrictions consistent with stopping the spread of COVID-19 in local communities.
- Mayors through executive orders, and/or local councils through amending extant housing, utilities, and employment laws, should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to stay-at-home orders, business and school closures, and gathering restrictions.

Courts:

- Courts should maintain the long-standing deference given to executive actions in the face of a public health emergency while protecting the public from measures based purely on fear, prejudice, or misinformation.



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References

In re Abbott, 954 F.3d 772 (2020).

Castillo, R. C., Staguhn, E. D., & Weston-Farber, E. (2020). The Effect of State-Level Stay-At-Home Orders on COVID-19 Infection Rates. *American Journal of Infection Control*. Retrieved July 23, 2020, from <https://doi.org/10.1016/j.ajic.2020.05.017>

Calvary Chapel Dayton Valley v. Sisolak, 591 U.S. ____ (2020).

Centers for Disease Control and Prevention (CDC)(2020). Health Equity Considerations and Racial and Ethnic Minority Groups. Retrieved August 3, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/race-ethnicity.html>

Gostin, L. O., & Wiley, L. F. (2020). Governmental Public Health Powers During the COVID-19 Pandemic: Stay-at-home Orders, Business Closures, and Travel Restrictions. *Journal of the American Medical Association*, 323(21), 2137-2138.

Jew Ho. v. Williamson, 103 F. 10 (C.C.D. Cal. 1900).

Maryville Baptist Church, Inc. v. Beshear, 957 F.3d 610 (2020)

New York v. New St. Mark's Baths, 497 N.Y.S.2d 979 (N.Y. Sup. Ct. 1986).

Parment, W. E. (2020). Rediscovering Jacobson in the Era of COVID-19. *Boston University Law Review Online*, 100, 117-133.

Slaughter-House Cases, 83 U.S. 36 (1873).

South Bay United Pentecostal Church v. Newsom, 140 S. Ct. 1613 (2020).

Wiley, L. F., & Vladeck, S. (2020). COVID-19 Reinforces the Argument for “Regular” Judicial Review—Not Suspension of Civil Liberties—In Times of Crisis. *Harvard Law Review Blog*. Retrieved July 23, 2020, from <https://blog.harvardlawreview.org/covid-19-reinforces-the-argument-for-regular-judicialreview-not-suspension-of-civil-liberties-in-times-of-crisis/>

Wisconsin Legislature v. Palm, 942 N.W.2d 900 (Wis. 2020).

Yearby, R., & Mohaptra, S. (2020). Law, Structural Racism, and the COVID-19 Pandemic. *Journal of Law and the Biosciences* (forthcoming). Retrieved July 23, 2020, from <https://doi.org/10.1093/jlb/lisaa036>

Surveillance, Privacy, and App Tracking

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SUMMARY. Over the last several months, global innovators have developed a heterogeneous array of “smart” technology protocols and applications aimed at tracking, tracing, and containing the spread of the novel coronavirus, SARS-CoV-2, which causes the disease COVID-19. The United States, which has left it to the states to acquire or build their own automated track and trace platforms, currently lags behind other countries. However, technology companies Apple and Google have announced co-production of a digital tracing platform for their phones. As this Chapter details, the United States lacks a comprehensive federal health data privacy law that protects the privacy of sensitive information collected and stored by digital contact tracking applications. The Chapter also explains how digital COVID-19 surveillance applications work, assesses their effectiveness from a public health perspective, and enumerates the legal and ethical issues they implicate. It concludes with proposals aimed at maximizing the public health benefits of COVID-19 surveillance technology while minimizing its inherent and conceivable threats to privacy, civil liberties, and vulnerable populations.

Introduction

Traditional contact or “case” tracing is a long-standing pillar of public health infectious disease prevention and mitigation dating back at least 500 years to medieval European bubonic plague outbreaks (Cohn & O’Brien, 2020). It is a multi-step process involving the deployment of an army of public health workers tasked with (1) identifying infected individuals; (2) interviewing infected individuals to identify others with whom they have had contact; and (3) testing and isolating those people to stem the tide of disease.

Government public health surveillance can detect and mitigate the spread of contagion, encourage health-enhancing behavioral, social, and environmental interventions, influence disease-mitigation law and policy, promote economic recovery, and protect high-risk populations (Gostin & Wiley, 2016). The system and its social benefits, however, are not without their detractors. Traditional contract tracing is expensive and resource intensive, and has been characterized as “slow,” “passive,” and “riddled with holes” (Shah, 2016).

Such holes are frequently exacerbated by traditional contact tracing’s necessary reliance on (1) accurate, widespread, and timely testing and (2) public trust in government sufficient to encourage meaningful screening, testing and reporting. The United States, which was criticized for its failure to widely screen its population early in its COVID-19 response, still lacks a unified national testing strategy. The states have stepped into the void and dramatically increased testing to track viral transmission and facilitate contact tracing as they have moved to reopen (Nuzzo, 2020).

The jury, however, is still out regarding the accuracy of screening tests (Modern Healthcare, 2020). Additional complicating factors include the notoriously long waits that have attended to tests results and the lack of any standardized national criteria as to what constitutes a COVID-19 “case” in the first instance. The threshold identification of a “case” subject to track and trace, therefore, is likely to vary across states as well as within states that have delegated such determinations to local government entities. Equally problematic, there is considerable public distrust in contact tracing in the United States due to political polarization and rampant social media disinformation (Appleby, 2020).

Even assuming the existence of a standardized definition of a “case,” fast, widespread, and accurate COVID-19 testing, and sufficient public trust to facilitate contact tracing, those who are asymptomatic and have not been tested have nothing to report. Individuals with mild to moderate symptoms also are disincentivized to subject themselves to screening, testing, and tracing because infectious disease surveillance can implicate the right to critical benefits, including access to employment, housing, and insurance (Gostin & Wiley, 2016). Because of the voluminous amount and sensitive nature of the data public health surveillance systems collect, traditional track and trace also raises ethical concerns that can disproportionately impact vulnerable groups, including low income and rural communities and individuals with legal status issues, stigmatizing co-morbid conditions or disabilities, and/or above-average contact with the criminal justice system.

These traditional contract tracing shortcomings have provoked American policymakers to look to digital containment tools,

including high-tech surveillance applications, to contain the spread of COVID-19. In April 2020, technology behemoths Google and Apple announced their co-production of application programming interfaces (APIs) for mobile Bluetooth technology surveillance to mitigate COVID-19 transmission. The voluminous proliferation of these digital surveillance applications precipitated the Massachusetts Institute of Technology's creation of a COVID Tracing Tracker to "capture every . . . automated contact tracing effort around the world," (O'Neill et al., 2020). As things currently stand, however, only four state public health authorities have reported that they intend to utilize Google/Apple exposure notification APIs (Hall, 2020).

Digital application surveillance is potentially cheaper and faster—and arguably more comprehensive and precise—than traditional track and trace because automated data collection does not rely on the limitations of human memory or reporting. Unfortunately, and as explained below, digital applications raise novel accuracy problems attributable to their underlying technology. They also routinely exclude high-risk individuals who lack access to technology and implicate heightened privacy and civil liberties concerns relative to traditional surveillance. The significant privacy and civil liberties risks raised by digital contact tracing technology are driven by a pair of intersecting factors. First, unlike traditional surveillance, which is conducted by health authorities for the exclusive purpose of containing infectious disease, most digital track and trace applications are the products of private technology companies whose business models have long been dependent on monetizing consumer data. Second, the constitutional and decades-old statutory health data privacy protections that extend to traditional health care actors in the United States generally do not apply to information collected and stored by private entities. The country's inadequate and patchwork-like health data protections laws are summarized in the following Section.

U.S. Health Data Privacy Law

Federal Constitutional Rights

While the U.S. Constitution does not expressly recognize a right to informational privacy, the Supreme Court identified a qualified right to health data privacy in *Whalen v. Roe*. At issue in *Whalen* was a New York statute that required physicians to report patient drug-prescribing information to the state department of health. Patients and physicians challenged the law on the grounds that it violated their Fourteenth Amendment rights to "nondisclosure of private information" (*Whalen v. Roe*, 1977). The Court rejected that argument but, in so doing, recognized that (1) individuals have Fourteenth Amendment privacy interests in their health data and (2) the compulsory disclosure of such data to a state public health agency satisfies the Fourteenth Amendment so long as the health agency safeguards the information it collects from public disclosure (Oliva, 2020).

The Supreme Court has also recognized that individuals have a reasonable expectation of privacy in their health data under the Fourth Amendment to the U.S. Constitution. In *Ferguson v. City of Charleston*, for example, the Court held that a state hospital violated patients' Fourth Amendment privacy rights by sharing

patients' diagnostic test records "with nonmedical personnel without [their] consent" (*Ferguson v. City of Charleston*, 2001). More recently, the Court held in *Carpenter v. United States* that individuals have a Fourth Amendment privacy interest in their cell site location information (CSLI) even when those records reveal public movements (*Carpenter v. United States*, 2018). These Fourteenth and Fourth Amendment privacy protections, however, apply only to government actors and not to the actions of private entities or employers. In addition, there are special needs and immigration-related exceptions to the Fourth Amendment warrant requirement that lessen privacy protections for individuals at or about the U.S. border (*United States v. Flores-Montano*, 2004).

HIPAA Privacy Rule

Unlike the European Union, which enacted the General Data Protection Regulation (GDPR) effective May 25, 2018, the United States lacks a comprehensive and effective data privacy law. The federal statute that is popularly synonymous with health information privacy is the Health Insurance Portability and Accountability Act. HIPAA however, only applies to a narrow sub-set of individually-identifying health data, which the statutory scheme refers to as "protected health information" (PHI), and a limited set of actors integral to the traditional health care payment system: health care providers, plans, clearinghouses, and their "business associates." HIPAA, which was enacted in advance of the advent of mobile devices and big data analytics, fails to extend to myriad private entities that collect, store, and sell health data, including digital health care application information (Terry, 2020).

The HIPAA Privacy Rule is riddled with numerous public purpose exceptions. Those exceptions allow covered entities to use and disclose PHI for, among other things, health oversight activities, judicial and administrative proceedings, law enforcement purposes, limited research activities, specialized government functions, and the aversion of serious threats to health or safety. Individuals who are justice involved and/or have legal status issues, therefore, are particularly vulnerable to nonconsensual HIPAA disclosures. HIPAA also fails to include a private right of action.

State Health Data Protection Laws

Adding to the complex patchwork of federal laws, several American states have recognized a state constitutional right to health data privacy, and most have developed statutory frameworks for data protection (Glenn, 2000; Terry, 2009). California recently adopted the most comprehensive state-level data protection regime in the United States by enacting the California Consumer Privacy Act (CCPA). While that law expressly exempts from its purview HIPAA-covered entities and health data governed by the state Confidentiality of Medical Information Act, it does apply to private digital application developers who conduct substantial business in California. It creates, among other things, the right to correct data, delete data, and privately enforce statutory privacy violations. The CCPA does not, however, extend to consumers any right regarding de-identified information.

The Exposure Notification Privacy Act

Congress has acknowledged that the above-described American privacy protection scheme is inadequate to safeguard individuals from the risks that attend to digital COVID-19 contact tracing applications. On June 1, 2020, two senators introduced the Exposure Notification Privacy Act (ENPA), which aims to “give [] Americans control over their data [and] put [] public health officials in the driver’s seat of exposure notification development.” ENPA is the third bill designed to protect health data privacy in the context of COVID-19 that Congress has introduced since April 30, 2020. The legislation requires automated exposure notification application operators to (1) collaborate with public health authorities, (2) obtain consent from enrolled users as well as a “clear and conspicuous” means to withdrawal such consent, (3) refrain from any data collection beyond that which is minimally necessary to implement the application, (4) abjure the use of such data for commercial purposes, (5) delete the data on regular intervals, and (6) permit users to request data deletion. The statute does not provide individuals with a private right of action to enforce its privacy protections.

COVID-19 Digital Surveillance & Tracking Technology

The two prevalent forms of automated contact tracing technology that have been designed and proposed for use to mitigate the spread of COVID-19 are location tracking applications and proximity tracking applications. Location tracking applications use global positioning system (GPS) and CSLI data generated by smartphones to track users’ physical movements. Location tracking applications are generally disfavored on both effectiveness and privacy grounds because, while GPS and CSLI-generated data are accurate enough to reveal troves of sensitive user information, it reliably fails to identify whether two individuals have engaged in close enough contact (six feet) to transmit COVID-19 (EFF, 2020). In addition, the Supreme Court has extended Fourth Amendment privacy protection to CSLI and GSP at least insofar as that data is collected and used for law enforcement purposes over an extended period of time. Whether the administrative search or special needs doctrines would exempt such data collected and used exclusively for public health surveillance purposes from Fourth Amendment purview is a more difficult and unsettled question.

Proximity tracking applications have emerged as the preferred option among developers and public health authorities. These applications use the strength of Bluetooth signals emitted by users’ smartphones to approximate the distance between two devices. Many proximity tracking designs, including the API protocols developed by Apple and Google, create a unique smartphone identifier and then routinely rotate those identifiers to enhance user privacy. Once a proximity application estimates that users are less than six feet apart for a sufficient period of time, it logs the interaction and exchanges the users’ unique identifiers between their phones. Proximity tracking need not involve the collection of users’ actual physical locations. The exposure notification system instead relies entirely on the length of time and proximity of user contacts generated by their smartphones’ Bluetooth signals.

It is at this stage of the data collection process that proximity tracking applications tend to vary. Some applications, such as Singapore’s “TraceTogether” technology are based on “top-down” or

“centralized” notification. These systems trust a central authority, such as a public health agency, with users’ contact (phone numbers, email addresses, etc.) and testing information. Once a TraceTogether user tests positive for COVID-19, that information is shared with the Singapore Ministry of Health, which, in turn, contacts each of the infected users’ logged contacts by phone or email.

Alternative approaches tend to be more decentralized and shelter more information from authorities. For example, in lieu of storing actual user contact information with a central authority, certain proximity tracking applications allow infected users to upload their own de-identified contact logs to a centralized database. The central authority then “notifies” or pings all at-risk users using each user’s unique identifier. Apple and Google’s joint approach goes even further. It creates a public database that broadcasts the unique identifiers of infected users to the smartphone applications of those with whom infected users come in close proximity.

The decentralized proximity tracking applications alleviate some—but not all—of the privacy concerns raised by governmental collection and storage of health data. Re-identification techniques are so widespread and effective, however, that the provision of even minimum personal data to a central authority via unsophisticated decentralized systems risks user identification. These concerns can and should be mitigated with robust encryption security safeguards.

Other pertinent issues that could undermine the efficacy of these systems pose more difficult challenges. First, and as alluded to above, proximity tracking applications are ineffective without fast, accurate, and widely available COVID-19 testing, which the United States does not currently have in place. Second, digital tracing applications cannot succeed without widespread adoption premised on public trust of the technology in the hands of governmental actors. “A recent simulation suggests the COVID-19 pandemic can be suppressed with 80% of all smartphone users utilizing the application, or 56% of the overall population,” and, as several renowned health law scholars recently warned, the U.S. “public is unlikely to accept mandates to implement digital tracing, even in a health emergency” (Cohen et al., 2020).

Third, proximity tracking applications risk both over- and under-inclusive exposure notification. They run into over-inclusivity issues because Bluetooth signals cannot meaningfully distinguish between individuals who actually come into prolonged and proximate contact and individuals who are separated by walls or are in different cars in parallel lanes on a road. The applications also cannot detect whether one or both of the users is wearing personal protective equipment (PPE). They are, therefore, likely to produce a high number of alerts for health care and other essential workers who frequently interact with others even when they are adequately protected with PPE.

Because they track the distance between smartphones and not the distance between human users, proximity tracking applications are also likely to generate under-inclusive exposure notifications. Users who fail to keep their smartphones on their persons when interacting with others are likely to be under-notified by the system as well as cause their contacts to be under-notified. In addition,

individuals whose interactions would qualify as a notification “contact” for digital tracing purposes will fall through the net to the extent that they are using different proximity applications.

More problematic, digital surveillance applications systematically exclude groups often at high-risk of COVID-19 exposure but least likely to have a smartphone and/or adequate data plan, including elderly people, low-income individuals, people with legal status issues, and individuals who live in rural communities. Digital track and trace systems, therefore, must offer these vulnerable groups free devices and data plans. Certain individuals are likely to opt out of even cost-free electronic surveillance. Low-wage and immigrant workers, for example, are at high-risk of non-participation because it is often impracticable for them to shelter in place for a two-week period and retain their employment and housing. Those with legal status issues or who are involved with the criminal legal/justice system are further incentivized to avoid surveillance out of fear of immigration authority and law enforcement reprisal. Finally, as noted above, a substantial segment of the American public will opt-out of digital track and trace because of their distrust of government monitoring.

Conclusion

The high value of protected health information, its extraordinary sensitivity, the United States’ lack of comprehensive health data protection laws and regulations, and significant efficacy and privacy issues raise serious concerns about digital contact tracing applications. Drawing from thoughtful discussions advanced by the Electronic Frontier Foundation, American Civil Liberties Union, European Data Protection Board, and International Association of Privacy Professionals, this Chapter concludes with a series of recommendations aimed at safeguarding against the risks posed to individuals by digital infectious disease surveillance while maximizing its public health benefits. 🌞

Recommendations for Action

Federal government:

- To facilitate appropriate use of technology in pandemic control, Congress should enact a statute that safeguards individuals from the risks that attend to digital COVID-19 contact tracing applications. Legislation should:
 - o Ensure user privacy;
 - o Assure informed, voluntary participation;
 - o Respect user autonomy;
 - o Prohibit discrimination and the dissemination of collected information to non-public health authorities;
 - o Prescribe the commercial use of collected data, mandate government transparency and accuracy, and guarantee data security;
 - o Include a sunset provision; and
 - o Extend to users a private right of action.

State governments:

- In the absence of federal action to facilitate appropriate use of technology in pandemic control, states should enact a statute that safeguards individuals from the risks that attend to digital COVID-19 contact tracing applications. Legislation should:
 - o Ensure user privacy including,
 - Data minimization;
 - Data deletion and correction;
 - Information security, including compliance with international data security best practices, encryption, conduct penetration tests and audited vulnerability assessments, and data breach notification; and
 - Extending to users a privacy right of action.
 - o Assure informed, voluntary participation.
 - o Respect user autonomy.
 - o Prohibit discrimination and the dissemination of collected information to non-public health authorities.
 - o Prescribe the commercial use of collected data, mandate government transparency and accuracy, guarantee data security.
 - o Include a sunset provision, and
- To ensure that contract tracing apps and processes do not reflect bias or infringe upon civil liberties and human rights, state governments by legislation or agency rule should ensure that as implemented:
 - o Applications neither (1) intentionally nor disparately burden folks on the basis of race, ethnicity, nationality, sex, religion, immigration status, LGBTQA+ status, or disability, nor (2) document information that implicates users' civil liberties or human rights
 - o Health authorities should provide no-cost cellular phones and data packages to individuals who wish to participate but do not have the resources to obtain the underlying technology, devices, and data plans
 - o Health authorities should incorporate the use of traditional contact tracers with local connections to vulnerable communities rather than solely rely on automated surveillance to ensure the inclusion of individuals who do not have access to smartphone technology and/or otherwise distrust digital surveillance.
- State governments (or, if it enters this space, the federal government) that implement digital contact tracing:
 - o Should also implement accurate, fast and widespread COVID-19 testing;
 - o Only adopt applications that are accurate enough that they assist rather than undermine traditional contract track and trace efforts;
 - o Should respect autonomy/informed consent:
 - Application usage should be voluntary and expressly permit users to opt-in and opt-out.
 - Application terms and conditions/user agreements should be clear and transparent and accessible to individuals with disabilities.
 - Application terms and conditions/user agreements should be translated into the most common languages and health authorities should ensure that translators are available to assist individuals to understand consent forms.
 - o Prioritize Anti-Bias, Civil Liberties, and Human Rights Protections
 - Applications should neither (1) intentionally nor disparately burden folks on the basis of

State recommendations, continued

race, ethnicity, nationality, sex, religion, immigration status, LGBTQA+ status, or disability, nor (2) document information that implicates users' civil liberties or human rights

- Health authorities should incorporate the use of traditional contact tracers with local connections to vulnerable communities rather than solely rely on automated surveillance to ensure the inclusion of individuals who do not have access to smartphone technology and/or otherwise distrust digital surveillance. As a recent EFF article explains, “[w]e cannot solve a pandemic by coding the perfect app. Hard societal problems are not solved by magical technology, among other reasons because not everyone will have access to the necessary smartphones and infrastructure to make this work,” (Crocker et al., 2020).

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References

Apple (2020). Apple and Google Partner on COVID-19 Contact Tracing Technology. Retrieved July 13, 2020, from <https://www.apple.com/newsroom/2020/04/apple-and-google-partner-on-covid-19-contact-tracing-technology/>

Appleby, J. (2020). Conspiracy Theories Aside, Here's What Contact Tracers Really Do. Retrieved July 28, 2020, from <https://californiahealthline.org/news/conspiracy-theories-aside-heres-what-contact-tracers-really-do/>

Blumenthal, D., & Blumenthal, R. (2020). Contact Tracing Must Balance Privacy and Public Health. Retrieved July 13, 2020, from <https://www.statnews.com/2020/05/15/contact-tracing-must-balance-privacy-and-public-health/>

California Consumer Privacy Act, California Civil Code § 1798.100-1798.199 (2018).

Carpenter v. United States, 138 S. Ct. 2206 (2018).

Children's Online Privacy Protection Act, 15 U.S.C. § 6501-6506 (1998).

Cohen I.G., Gostin, L.O., & Weitzner, D.J. (2020). Digital Smartphone Tracking for COVID-19: Public Health and Civil Liberties in Tension. *Journal of the American Medical Association*, 323(23), 2371-2372. Retrieved July 13, 2020, from <https://jamanetwork.com/journals/jama/fullarticle/2766675>

Cohn, S., & O'Brien, M. (2020). Contact Tracing: How Physicians Used it 500 Years Ago to Control the Bubonic Plague. Retrieved July 13, 2020, from <https://theconversation.com/contact-tracing-how-physicians-used-it-500-years-ago-to-control-the-bubonic-plague-139248>

Crocker, A., Opshal, K., & Cyphers, B. (2020). The Challenge of Proximity Apps for COVID-19 Contact Tracing. Retrieved July 28, 2020, from <https://www.eff.org/deeplinks/2020/04/challenge-proximity-apps-covid-19-contact-tracing>

Electronic Frontier Foundation. (2020). Guide to Digital Rights During the Pandemic: An eBook. Retrieved July 13, 2020, from <https://www.eff.org/pages/guide-digital-rights-pandemic>

Exposure Notification Privacy Act, S.3861, 116th Cong. (2020).

Family Educational Rights and Privacy Act, 10 U.S.C. §1232g (2013).

Ferguson v. City of Charleston, 532 U.S. 67 (2001).

Glenn, C.L. (2000). Protecting Health Information Privacy: The Case for Self-Regulation of Electronically Held Medical Records. *Vanderbilt Law Review*, 53(5), 1605-1635.

Gostin, L.O., & Wiley, L.F. (2016). *Public Health Law: Power, Duty, Restraint*. Oakland, CA: University of California Press.

Hall, Z. (2020). Which U.S. States are Using Apple's Exposure Notification API for COVID-19 Contact Tracing? Retrieved July 28, 2020, from <https://9to5mac.com/2020/07/13/covid-19-exposure-notification-api-states/>

Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, 110 Stat. 1936 (1996).

Johnson, B. (2020). The US Draft Law on Contact Tracing Apps is a Step Behind Apple and Google. Retrieved July 13, 2020, from <https://www.technologyreview.com/2020/06/02/1002491/us-covid-19-contact-tracing-privacy-law-apple-google/>

Modern Healthcare (2020). Accuracy of COVID-19 Tests Still Largely Unknown. Retrieved July 13, 2020, from <https://www.modernhealthcare.com/technology/accuracy-covid-19-tests-still-largely-unknown>

Nuzzo, J.B. (2020). No, More Testing Doesn't Explain the Rise of COVID-19 Cases in the U.S. *Washington Post*. Retrieved July 13, 2020, from <https://www.washingtonpost.com/outlook/2020/06/22/no-more-testing-doesnt-explain-rise-covid-19-cases-us/>

O'Neill, P.H., Ryan-Mosley, T., & Johnson, B. (2020). A Flood of Coronavirus Apps are Tracking Us. Now It's Time to Keep Track of Them. Retrieved July 13, 2020, from <https://www.technologyreview.com/2020/05/07/1000961/launching-mittr-covid-tracing-tracker/>

Oliva, J.D. (2020). Prescription-Drug Policing: The Right to Health-Information Privacy Pre- and Post-Carpenter. *Duke Law Journal*, 69(4), 775-853.

Privacy Act, 5 U.S.C. § 552a (1974).

Shah, S. (2016). *Pandemic: Tracking Contagions, from Cholera to Ebola and Beyond*. New York, NY: Picador.

Terry, N.P. (2009). What's Wrong with Health Privacy? *Journal of Health and Biomedical Law*, 5(1), 1-32.

Terry, N.P. (2020). Assessing the Thin Regulation of Consumer-Facing Health Technologies. *Journal of Law, Medicine and Ethics*, 48(S1), 94-102.

United States v. Flores-Montano, 541 U.S. 149 (2004).

Whalen v. Roe, 429 U.S. 589 (1977).

Conducting Elections During a Pandemic

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SUMMARY. At the beginning of 2020, many believed that the biggest threat to our elections was foreign interference, consistent with disinformation campaigns launched by our adversaries. But even with this lingering threat, it was expected that voter turnout in the 2020 presidential election would break records – perhaps even reaching the highest level of turnout since the nation saw more than 65% of eligible voters participate in the election of 1908, over a century ago (USEP, 2020). The onset of the pandemic brought much uncertainty, as election officials faced unprecedented challenges, unsettled law, and diminishing resources, while voters were torn between concern about our democracy and fear of contracting COVID-19. Widespread shortages of poll workers and safe polling locations, rushed transitions to mail voting, and insufficient funding could not diminish the democratic spirit, however, and we’ve seen primary turnout break records in some states. Most experts in the field believe that we should plan for the highest turnout in generations this fall, even as we expect that restrictions and fears due to the pandemic will be in full force. What’s also apparent, however, is that law, policy, and perhaps most importantly, administrative and informational practices in our highly decentralized administration of elections are not yet fully equipped to facilitate safe, secure, and convenient voting for 150 million Americans in the midst of a global health crisis. And while solutions like expanding mail voting will be necessary, no one solution will solve this problem, nor will all states find themselves able to offer the same options to all voters. We will need a multifaceted approach including easy mail voting, a massive recruitment of new poll workers to allow for safe and convenient in-person voting, and an unparalleled voter education effort to meet this challenge.

Introduction

By the beginning of March 2020, voters and election officials were feeling the effects of COVID-19 in the primary elections, including polling place closures, poll worker cancellations, and shifts to mail voting. A week after Super Tuesday voters were becoming increasingly concerned about the March 10, 2020 Michigan primary, which may have contributed to record mail voting in that election. By March 17, 2020, the pandemic’s impact on the primaries was palpable. While Arizona, Florida, and Illinois went forward with their primaries, Ohio saw a state court deny an order to postpone the primary, followed by an emergency executive order to postpone coming from the director of the Ohio Department of Health just hours before voting was to begin (Smith, 2020). Georgia followed suit, postponing its primary scheduled for March 24, 2020. Other than Wisconsin (which held its primary as scheduled on April 7, 2020, after much legal wrangling and confusion) and Ohio (which held its rescheduled primary on April 28, 2020, almost entirely by mail after the legislature disagreed with the election officials in the state), every other state with a scheduled primary in April 2020 postponed it. By July 2020, however, most states have held their presidential primaries, and we have learned some clear lessons about holding elections during a pandemic.

Lessons Learned from Primary Elections During the Pandemic

Resources are Lacking

A lack of resources seems to be the one constant from every one of these primaries. First and foremost among these is a shortage of poll workers. Typically, for a presidential general election, our nation relies upon more than one million volunteers to staff all the polling places and facilitate voting. Most poll workers in the United States are over the age of 60, the highest risk group for COVID-19 (Barthel & Stocking, 2020). Every single state has seen vast shortages of poll workers, and last-minute cancellations by those who had previously volunteered. And those volunteers who do staff the polls are often without adequate training, as in-person trainings are no longer held, and some get recruited at the last minute. Without an adequate number of poll workers, fewer polling locations can be open, and voters wait longer to vote.

In addition, even if an adequate number of poll workers can be recruited and trained, states are suffering from a lack of appropriate polling sites, which could lead to voters having fewer places to vote, or having to travel farther than usual. Polling

places are usually placed in local neighborhoods, close to the voters assigned to them, but many of them may be too small to accommodate social distancing or are located close to at-risk populations, like senior citizens. Schools may not be appropriate depending on the status of the school system. This means that states and counties are consolidating precincts, and that many more voters will vote in each site, and often at a location with which they are unfamiliar.

Finally, holding elections during a pandemic is more costly. As voting rules may change (sometimes at the last minute), polling places are relocated, and there are new options for voters (like voting by mail), the need for constant communication with voters becomes more critical and more expensive. States like Georgia, Iowa, and Michigan sent mail ballot applications to all voters in advance of their primaries, successfully boosting mail voting turnout and easing burdens on polling places but spent millions of dollars in the process. And as states are seeing vast revenue reductions in light of the pandemic, state election offices are seeing budget cuts just as the need for more funding becomes more crucial. Congress appropriated \$400 million earlier this year, but that fails to fulfill the dire needs of the states.

Toxic Partisanship is Poisoning the System

As demand for safer voting options increases, so too are the efforts of partisan politicians to game the system. This is most prominent in the false claims coming from President Trump that mail voting will somehow lead to “rigged” elections, despite the fact that the president, vice president, and many others in the White House all vote by mail (Steinhauser, 2020). There are basically three different approaches to mail voting in the United States. First, “universal” mail voting, where all registered voters receive a ballot in the mail, which is the system in place in Colorado, Hawaii, Oregon, Utah, and Washington, and the one likely to be implemented in California, Nevada, and Vermont this fall. Second, “no excuse” mail voting is in place in the vast majority of states, where any voter can request a mail ballot for a particular election, without needing any excuse. Finally, “excuse required” mail voting, where a voter may request a mail ballot but must provide a specific excuse, such as illness or travel, is the system in a minority of states, including Texas, though some states, such as Alabama, have extended excuses to include those related to COVID-19.

While almost all election officials of both parties are putting voters first and offering more options to vote safely (either by mail or in person), the partisanship does not stop at the White House. In Georgia, Iowa, and Ohio, Republican secretaries of state all requested more flexibility to offer options to their voters during the pandemic, only to have their Republican-dominated legislatures deny their requests. And Democrats are not immune, with some anticipatorily claiming “vote suppression” and possibly dissuading voters from participating in places like Kentucky where the primary election went particularly smoothly (Montellaro, 2020).

It is difficult enough to run an election in perfect circumstances, given the distrust that much of America feels for the rest, and other divisions that run through American society. But in a

pandemic, it becomes exponentially more challenging. Add in the constant factor of foreign interference and disinformation, where adversaries use our division against us, to diminish our confidence in elections, and we have a perfect storm. We will need partisans to put their immediate, selfish interests aside to put voters first and allow their voices to be heard.

The Courts are Struggling

We have never before held elections in an environment where voters are both enthusiastic to participate and fearful of infection at the same time, with shortages of poll workers and polling sites, diminished resources, and the constant threat of foreign interference. While there is no historical precedent for holding a presidential election in this environment, there are two legal precedents that could apply. First, the *Anderson-Burdick* test which states that if an election law imposes a “severe burden,” strict scrutiny applies when determining whether the election procedure unduly burdens the fundamental right to vote. (*Anderson v. Celebrezze*, 1983; *Burdick v. Takushi*, 1992). Second, the *Purcell* principle, which restricts the ability of states to impose changes to election procedures close to an election (*Purcell v. Gonzalez*, 2006). While the *Burdick* test results in the most comprehensive balancing of interests, when an election law change has been made in close proximity to an election (as we now find ourselves less than three months before voting ends), courts have tended to give the *Purcell* principle precedence. However, our current situation is unique, and while *Purcell* has typically applied to last-minute changes that could burden voters’ rights, we are in many cases seeking to evaluate emergency provisions to ease burdens on voting during a crisis like the pandemic.

In just the last few months, we have seen several courts, at both the state and federal level, deal with changes to voting procedures in different, often in contradictory ways. In Ohio, the state court declined to postpone the March 17, 2020 primary at the governor’s and secretary of state’s request, leaving the director of the Ohio Department of Health to postpone the primary at the last minute by executive order (Corasaniti & Saul, 2020). The Ohio Supreme Court then upheld the postponement order just hours before the polls were to be opened.

In Wisconsin, less than 24 hours before the polls were to open, the state supreme court overturned the governor’s order to postpone the April 7, 2020 primary, while the U.S. Supreme Court intervened to overturn a lower court order extending the time to count mail ballots (Neely, 2020). And most recently in Alabama, the U.S. Supreme Court in a 5-4 vote reversed a lower court ruling that eased the mail ballot requirements for voters, reinstating some of the toughest mail balloting restrictions in the nation that required a notary or two witnesses to verify every ballot and a copy of photo identification to be included even during the pandemic (Barnes & Viebeck, 2020).

Both of these cases were largely decided on the basis of administrative law and separation-of-powers doctrines, and given the flexibility states have to dictate how and when candidates are nominated in primaries and caucuses, the states (and the political

parties) had some degree of flexibility. But as states prepare for the general election, the stakes are higher, and despite tweets from the president, (Shabad, 2020), the voting in the 2020 election will be completed on November 3, 2020 (National Task Force on Election Crises, 2020). We are beginning to see more cases involving executive or legislative authority to ease voting requirements due to COVID-19, including sending ballots to all voters, easing mail ballot witness/notary requirements, early voting options, polling place locations, and other considerations (Levitt, 2020).

While it is understandable that courts are reticent to change election policy, particularly in light of the *Purcell* principle, it is also clear they have not quite determined their proper role during this unprecedented situation. Voters want to participate but they are also scared, and it may be that, with toxic partisanship and a lack of resources, courts need to reconsider their role and be more willing to apply a *Burdick* test to balance which measures are necessary to facilitate the right to vote, while maintaining the integrity of the ballot, and which may be superfluous given the strong interest in each individual's right to vote.

What Must Happen in November?

COVID-19 raised challenges during the middle of the primary calendar with little time to address those challenges, creating significant problems. However, it also enabled us to view those problems during elections that were, in essence, nominating contests with relatively low turnout. In some ways, we may be fortunate that the pandemic's effects were first felt early this year rather than in the fall, enabling us time to build further resilience into our election system. However, a presidential general election will see turnout at least double, if not triple, that of the primaries, and partisan tensions will be higher. Preparing for the election now — and defining how to measure success for this election — will be crucial.

Over the last half century, perhaps contrary to conventional wisdom, it has become easier to vote than ever. Registering to vote is simpler, with 39 states and the District of Columbia offering online voter registration (NCSL Online Voter Registration, 2020), while 19 states and the District of Columbia have passed automatic voter registration (NCSL Automatic Voter Registration, 2020). Thirty states and the District of Columbia belong to the Electronic Registration Information Center (ERIC), which enables states to reach out to potentially eligible voters for registration and keep state voter lists more up-to-date (ERIC, 2020). Voters in 21 states and the District of Columbia have access to same-day voter registration, where they can register and vote at the same time (NCSL, 2019). And easy mail voting and early voting is available to more voters than ever before in the vast majority of states (NCSL Polling Place, 2020).

We are fortunate that the election environment is more voter-centric than ever but, given the challenges related to the pandemic, voters must have access to different voting options and be made aware of those options. While no-excuse mail voting is available to most voters in the country, it is common in most states for most voters to vote in person. Many states, including Georgia, Kentucky,

North Carolina, Pennsylvania, and Wisconsin, have traditionally seen less than 10% of all ballots returned by mail. Several of these states, including Georgia and many others, saw record numbers of mail ballots during the primaries, often driven by mailing mail ballot applications to all voters. States are considering ways to continue easing the mail voting process, including mailing applications to all voters again (as Michigan is doing) or creating an online mail ballot application portal (as in Georgia).

But mail voting is not for everyone, and it will not save us from the pandemic. Mail voting requires significant advance planning, can lead to voter errors, and is unfamiliar to many. Even in states where election officials have actively promoted mail voting, millions of voters have chosen to vote in person, even during a health crisis. No matter how many mail ballots are requested, election officials should plan for a very large number of citizens voting in person. Officials should promote early in person voting for those that prefer or need to vote in a polling place. Where possible, states should expand early voting hours and locations to try to direct more in-person voting to before Election Day so that we can facilitate safe, convenient in person voting options that minimize the need for large numbers of people to congregate together at the same time.

As discussed above, as a nation we have relied upon an army of more than a million, primarily older poll workers to facilitate elections. But in the current environment, that isn't safe, desirable, or possible. We must find new ways to engage younger, healthy individuals to help run our elections, many of whom may bring important skillsets, like technology or language skills, to the process. This will require a new effort in partnering with the business community, colleges and universities, and others to recruit a new generation of poll workers. Businesses should offer paid time off and schools should offer credit for poll worker service and training and promote poll worker service via their platforms. States should create central, online poll worker sites to make it easy to volunteer.

Along these lines, we will need rethink the vision of the 21st century polling place. Polling places this year, and perhaps for the foreseeable future, will need to be larger to accommodate distancing and consolidation of many precincts under a single roof. A model may be the mega-voting-center that was created in Louisville, KY, at the Kentucky Expo Center, where thousands of voters voted in the primary. Sites with large, open areas that accommodate distancing and are centrally located with ample parking and access to public transportation are especially ideal. States are already planning to adopt this model for early voting (and perhaps Election Day voting), partnering with the NBA to use their arenas in cities like Atlanta, Detroit, and Milwaukee (Parks & Swasey, 2020). When appropriately staffed, such sites enable hundreds or thousands of citizens to vote with minimal lines and sufficient social distancing.

Perhaps most importantly, election officials should begin identifying appropriate voting sites and recruiting and training poll workers immediately. This should include recruiting and training far more poll workers and securing more voting sites than they anticipate needing. No matter how much states promote mail

voting, tens of millions of Americans are going to need safe and convenient locations to vote in person.

Regardless of how each state plans to meet the challenges of the pandemic, one thing is certain: voters will experience many changes to the election process that they may not be prepared for, particularly if they are less-frequent voters. Election rules, polling places, deadlines, etc., all could change, in some cases quite rapidly. Election officials and other groups will need to engage in the most broad-based voter education campaign in our nation's history, regularly communicating with voters. This is even more crucial since we are still operating in an environment where foreign adversaries are spreading disinformation to weaken confidence in our democracy.

We live in an environment where we need to plan for everything, from something as trivial as a trip to the grocery store to things as significant as expressing our democratic voice. While each voter may have the right to register or request a mail ballot at the deadline or get in line to vote minutes before the polls close, that is not a recipe for success. Thus, while we're focused appropriately on the preparedness of election officials, we will also have to prepare the electorate so they can plan to vote in a way in which they're most comfortable, and which maximizes the success of their voting experience.

While the \$400 million that Congress already appropriated to the states (as part of the CARES Act) is a good start, covering some expenses from the primaries, it is woefully inadequate to fund necessary efforts for the fall. Election officials across the political spectrum agree that we will need billions of dollars to recruit enough poll workers, secure appropriate polling locations, keep our electorate informed, and process the 150 million ballots that will be cast through various means. Particularly as state budgets are stretched, we will need the federal government to step up and assist the states in administering the upcoming federal election.

Unfortunately, most Americans and the media have somewhat unrealistic expectations for elections, even in the best of circumstances. Any time where 150 million Americans are doing the same thing, nationwide, in a system run by volunteers, there are bound to be some problems and delays. While there are significant instances, even today, of barriers to the franchise (sometimes intentionally-placed to affect traditionally-disenfranchised groups), most voting issues are not the result of intentional malfeasance, voter suppression, or partisan manipulation. Many problems that occur are merely the natural result of an imperfect system under stress; our adversaries know this, and seek to inflame concerns about lines and other problems to further diminish voter confidence. During a pandemic, we are exceptionally vulnerable to such machinations and we should be especially patient, understanding that those running elections are public servants — our neighbors and fellow citizens — doing the best they can under trying circumstances.

Patience will be doubly required when it comes to waiting for election results. While we normally expect results just hours (or minutes) after the polls close, those expectations cannot be met as we expand mail voting much more widely. Many ballots won't be processed until after the polls close, and results may not be available in some states until days after the election. Election officials and the media have been responsible in resetting these expectations, and that must continue, particularly as foreign governments may seek to sow further discord by alleging that the normal, if time-consuming, process of legitimately counting ballots is somehow evidence of fraud. 🦠

Recommendations for Action

Federal government:

- Congress must fund the administration of the forthcoming election. As state budgets are stretched, the federal government must step up and assist the states in administering the upcoming federal election during the public health emergency.

State governments:

- Legislatures or the executives should expand voter options to include easy mail and early voting.
- Election officials should prioritize efforts to recruit new poll workers and provide an adequate number of convenient and appropriate voting locations.
- Election officials should embark on an historic voter education initiative to foster understanding of the challenges caused by the pandemic and the changes that will follow. In particular, officials should reset expectations regarding the time that may elapse before results are known.

Courts:

- Courts need to reconsider their role and be more willing to apply a *Burdick* test to balance which measures are necessary to facilitate the right to vote, while maintaining the integrity of the ballot.



About the Author

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References

- Anderson v. Celebrezze, 460 US 780 (1983).
- Barnes, R., & Viebeck, E. (2020). Supreme Court says Alabama does not have to loosen ballot restrictions because of virus. *Washington Post*. Retrieved July 17, 2020, from https://www.washingtonpost.com/politics/courts_law/supreme-court-says-alabama-does-not-have-to-loosen-ballot-restrictions-because-of-virus/2020/07/02/fd7d32de-bcca-11ea-8cf5-9c1b8d7f84c6_story.html
- Barthel, M., & Stocking, G. (2020). Older people account for large shares of poll workers and voters in U.S. general elections. *Pew Research Center*. Retrieved July 17, 2020, from <https://www.pewresearch.org/fact-tank/2020/04/06/older-people-account-for-large-shares-of-poll-workers-and-voters-in-u-s-general-elections/>
- Burdick v. Takushi, 504 U.S. 428 (1992).
- Corasaniti, N., & Saul, S. (2020). Ohio's Governor Postpones Primary as Health Emergency Is Declared Over Virus. *The New York Times*. Retrieved July 17, 2020, from <https://www.nytimes.com/2020/03/16/us/politics/virus-primary-2020-ohio.html>
- Electronic Registration Information Center (ERIC)(2020). Retrieved July 17, 2020, from <https://ericstates.org/>
- Levitt, J. (2020). The list of COVID-19 election cases. Retrieved Aug. 3, 2020, <https://electionlawblog.org/?p=111962>
- Montellaro, Z. (2020). Coronavirus threatened to make a mess of Kentucky's primary. It could be a model instead. *Politico*. Retrieved July 17, 2020, from <https://www.msn.com/en-us/news/politics/coronavirus-threatened-to-make-a-mess-of-kentuckys-primary-it-could-be-a-model-instead/ar-BB16kIZL?li=BBnbfCL>
- National Conference of State Legislatures (NCSL)(2019). Same Day Voter Registration. Retrieved July 17, 2020, from <https://www.ncsl.org/research/elections-and-campaigns/same-day-registration.aspx>
- National Conference of State Legislatures (NCSL Automatic Voter Registration)(2020). Automatic Voter Registration. Retrieved July 17, 2020, from <https://www.ncsl.org/research/elections-and-campaigns/automatic-voter-registration.aspx>
- National Conference of State Legislatures (NCSL Online Voter Registration)(2020). Online Voter Registration. Retrieved July 17, 2020, from <https://www.ncsl.org/research/elections-and-campaigns/electronic-or-online-voter-registration.aspx>
- National Conference of State Legislatures (NCSL Polling Place)(2020). Voting Outside the Polling Place: Absentee, All-Mail and other Voting at Home Options. Retrieved July 17, 2020, from <https://www.ncsl.org/research/elections-and-campaigns/absentee-and-early-voting.aspx>
- National Task Force on Election Crises (2020). Can the President Cancel or Postpone the General Election? <https://static1.squarespace.com/static/5e70e52c7c72720ed714313f/t/5f22c800c516197500f1c997/1596114945315/ElectionTimingGuide.pdf>
- Neely, B. (2020). Wisconsin Plans To Vote In Person Tuesday After Last Minute Chaos. *NPR*. Retrieved July 17, 2020, from <https://www.npr.org/2020/04/06/828191015/wisconsin-governor-effectively-reschedules-tuesdays-primary-election>
- Parks, M., & Swasey, B. (2020). Need A Polling Place With Social Distancing? 3 NBA Teams Offer Venues. *NPR*. Retrieved July 17, 2020, from <https://www.npr.org/2020/07/02/886566523/need-a-polling-place-with-social-distancing-3-nba-teams-offer-venues>
- Purcell v. Gonzalez, 549 U.S. 1 (2006).

Shabad, R (2020), Trump floats delaying the election, but he can't do that. *NBC*. Retrieved Aug. 3, 2020, <https://www.nbcnews.com/politics/2020-election/trump-suggests-delaying-2020-election-n1235300>

Smith, A. (2020), Ohio primary called off at last minute because of health emergency. *NBC*. Retrieved Aug. 3, 2020, <https://www.nbcnews.com/politics/2020-election/ohio-governor-calls-state-postpone-tuesday-s-primary-elections-n1160816>

Steinhauser, P. (2020). Trump claims mail-in ballots 'will be printed by foreign countries.' *Fox News*. Retrieved July 17, 2020, from <https://www.foxnews.com/politics/trump-claims-mail-in-ballots-will-be-printed-by-foreign-countries>

United States Election Project (USEP)(2020). National General Election VEP Turnout Rates, 1789-Present. Retrieved July 17, 2020, from <http://www.electproject.org/national-1789-present>

PART 2

**Fulfilling Governmental
Responsibility in a Federal System**

Summary of Recommendations for Fulfilling Governmental Responsibilities in a Federal System

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Fulfilling Governmental Responsibilities in a Federal System* concern the challenges of vigorous pandemic control in a federal system and tightly networked world. Topics addressed include preemption, immigration enforcement, and international cooperation. Recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal, state, local and Tribal guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic.

Action at the Federal Level

- Congress and the White House should jointly convene an independent commission of inquiry to conduct a thorough public investigation of the federal and state government preparation for and response to COVID-19 (Anderson and Burris, Assuring)
- To strengthen the state and local response to COVID-19, Congress should use its appropriations power to
 - o Provide more funding to state, Tribal and local governments to fill COVID-19 related budget gaps and to implement supports, accommodations, and legal protections to enable individuals, families, employers, landlords, school systems and local communities to comply with social distancing recommendations and restrictions
 - This financial support should not be conditioned on adopting a less cautious approach to social distancing restrictions (including school closures) or face covering requirements
 - o Provide more funding to state, Tribal and local governments to support testing and contact tracing (Silverman, Contact Tracing; Wiley, Federalism; Hoss and Tanana, Upholding Tribal Sovereignty; Gable, Mass Movement)
 - Funding should require the employment of a culturally sensitive, linguistically competent contact-tracing workforce reflecting the make-up of the community (Silverman, Contact Tracing)
- To better support Tribal pandemic response efforts, the federal government should
 - o Honor trust responsibility and consultation requirements as outlined by federal law
 - o Provide funding directly to Tribes rather than through Tribal-serving organizations
 - o Provide funding mechanisms directly to Tribes at rates equal to or higher than those provided to states and local governments
 - Do not delay in the distribution of such funds
 - Do not use Tribal-serving organizations or entities as proxies for funding directly to Tribes
 - o Require state and local government recipients of COVID-19 grants and cooperative agreements to meaningfully consult with Tribes in the disbursement of funds or services and to document such consultation as a condition of funding
 - o Sufficiently fund Indian Health Service, Tribal health facilities, and Urban Indian health centers
 - o Provide more stable funding for other Indian health programs, including permanently reauthorizing the Special Diabetes Program for Indians (Hoss and Tanana, Upholding Tribal Sovereignty)
- To prevent unnecessary international spread of the pandemic, ICE should cease deporting individuals who are infected with COVID-19 (Parmet, Immigration)
- Congress should take vigorous action to reverse the president's decision to withdraw from the WHO, including
 - o Immediately hold hearings on the legal authority and potential impacts of the president's decision to withdraw from WHO
 - o Pass a joint resolution that 1) formally disapproves of President Trump withdrawing from WHO, establishing the clear conflict with the executive that would provide the grounding for a legal challenge, 2) requires continued participation in WHO, and 3) affirms its interpretation of the 1948 joint resolution: that WHO withdrawal would require joint executive and congressional approval
 - o If the president vetoes the resolution, Congress could

override the veto. Alternatively, Congress could pass a concurrent resolution, which does not require presidential signature, though lacks force of law. Either action would bolster Congress's position that a unilateral withdrawal violates separation of powers principles

- o Lastly, Congress should pass a resolution to authorize litigation against the president to block withdrawal action (Wetter and Friedman, US Withdrawal)
- Congress should continue to appropriate funding WHO action (Wetter and Friedman, US Withdrawal)
- The federal government should support essential policy experimentation by minimizing preemption or other interference with reasonable local control measures (Anderson and Burris, Is Law Working)
- The president should appoint, and the Senate only confirm, judges receptive to legal theories protective against the misuse of state and federal preemption (Haddow et al., Preemption)
- Congress must fund the administration of the forthcoming election. As state budgets are stretched, the federal government must step up and assist the states in administering the upcoming federal election during the public health emergency (Becker, Elections)
- Courts need to reconsider their role and be more willing to apply a Burdick test to balance which measures are necessary to facilitate the right to vote, while maintaining the integrity of the ballot (Becker, Elections)

Action at the State Level

- States should consider amending their constitutions and/or statutes imposing balanced budget requirements to permit deficit spending in times of crisis (Wiley, Federalism)
- State governments should permanently remove state preemption of more protective local laws related to COVID-19 response (eg, mask and physical distancing mandates), economic security (eg, minimum wage, paid leave, employment protections), equitable housing (eg, eviction moratoria, rent control, source-of-income antidiscrimination), municipal broadband, and civil rights (eg, antidiscrimination laws, sanctuary cities)
 - o Governors and other authorized officers should use their emergency powers to suspend preemptive laws preventing effective and equitable local responses
 - o Where necessary, state legislatures should amend state emergency laws to authorize the suspension of preemptive laws
 - o Legislatures should remove state preemption of more protective local laws related to COVID-19 response (eg, mask and physical distancing mandates), economic security (eg, minimum wage, paid leave, employment protections), equitable housing (eg, eviction moratoria, rent control, source-of-income antidiscrimination), municipal broadband, and civil rights (eg, antidiscrimination laws, sanctuary cities)

(Haddow et al., Preemption; Anderson and Burris, Is Law Working; Lawton, COVID-19; Gable, Mass Movement)

- Legislatures should repeal all state preemption laws that penalize localities or local officials that enact, enforce, or attempt to enact or enforce preempted or potentially preempted laws (eg, laws subjecting localities and local officials to fines, civil liability, removal from office, and loss of funding)(Haddow et al., Preemption)
- Legislatures, and voters in states that allow voter initiatives, should adopt structural reforms to strengthen home rule in alignment with the National League of Cities Principles of Home Rule for the 21st Century (Haddow et al., Preemption)
- Those responsible for appointing judges, and voters in states that elect judges, should select judges receptive to legal theories protective against the misuse of state preemption (Haddow et al., Preemption)
- Legislators or the executives should expand voter options to include easy mail and early voting
 - o Election officials should prioritize efforts to recruit new poll workers and provide an adequate number of convenient and appropriate voting locations (Becker, Elections)
- State governments should respect Tribal authority and jurisdiction to promote the health and welfare of their communities and to implement COVID-19 response measures on their lands, including curfews, checkpoints, mask wearing, and other requirements
- State governments should enact law to require consultation with Tribes if the state or local government is making law or policy that impacts the Tribe
- To better support Tribal pandemic response efforts, agencies should
 - o Consult with Tribes on any matters that impact Tribal communities
 - o Work with Tribal governments to enter into data sharing and mutual aid agreements or memoranda of understanding without requiring Tribes to waive sovereign rights as a condition of these agreements
 - o Share COVID-19 related public health data with Tribes (Hoss and Tanana, Upholding Tribal Sovereignty)

Action at the Local Level

- Local governments and residents should support resolutions, lobby state lawmakers, and call for state executive action in support of local authority to enact more protective laws related to COVID-19 response (eg, mask and physical distancing mandates), economic security (eg, minimum wage, paid leave, employment protections), equitable housing (eg, eviction moratoria, rent control, source-of-income antidiscrimination), municipal broadband, and civil rights (eg, antidiscrimination laws, sanctuary cities)(Haddow et al., Preemption)

- Local governments and residents should advocate for state legislation or ballot measures expanding home rule authority in alignment with the National League of Cities Principles of Home Rule for the 21st Century (Haddow et al., Preemption)
- Election officials should prioritize efforts to recruit new poll workers and provide an adequate number of convenient and appropriate voting locations (Becker, Elections)

Action at the Tribal Level

- Tribal governments should consider entering into data sharing and mutual aid agreements or memoranda of understanding with neighboring jurisdictions, Tribal Epi Centers, and clinics to support and coordinate COVID-19 responses, working with Tribal counsel to ensure that Tribal sovereign rights are not compromised in such agreements (Hoss and Tanana, Upholding Tribal Sovereignty)

Executive Decision Making for COVID-19: Public Health Science through a Political Lens

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SUMMARY. Executive decision making is the crux of using law to achieve public health objectives. But public health codes and emergency declaration laws are not self-executing. In this chapter, we examine how elected officials and public health officers have used their legal authority to address the COVID-19 pandemic. We begin with an overview of an executive decision-making tool for public health officials. Then we describe the general legal background in which these decisions have been made. Next, we apply the decision-making tool to how governors in eight states have determined whether to issue stay-at-home orders and when to relax these restrictions. In this section, we focus on the criteria governors used to re-open the state's economy and additional restrictions, such as mask wearing, as a condition of reopening. We examined the states' political party control, the use of public health science, and equity considerations. We conclude that the COVID-19 response represents federalism at work, with considerable variation across the sample states, and that the public health science is filtered through a very thick political lens. In short, governors making political decisions drove the process, not public health officials relying on the best available science. We conclude with recommendations for future action.

Introduction

Governors and local elected officials are using their legal authority to issue a range of emergency orders to combat the spread of COVID-19. These orders include stay-at-home requirements, mask wearing in public, and closing non-essential businesses. In most instances, elected officials are relying on state and local public health professionals to provide advice on whether to issue a particular set of restrictions and when to relax or terminate the order.

Addressing situations posing a threat to the community's health is the core of a public health director's decision-making responsibility. As the health officer for a state, Tribal, county, or local health department, the executive is called upon to use professional judgment, informed by scientific evidence, to take the best course of action within the agency's legal authority or make appropriate recommendations to elected officials.

This chapter focuses on how public health officials exercise that judgment in working with elected officials to mitigate the spread of COVID-19. Because the pandemic spreads differently across and within states, COVID-19 demonstrates the importance of the relationship between science and politics. But COVID-19 also illustrates the difficulty of decision-making with a novel virus and rapidly changing advice from federal governmental virologists and public health officials.

The Executive Decision-Making Tool

As we discuss below, elected officials and public health leaders have considerable discretion under most state public health codes in which their decisions must be made. To exercise their broad grant of authority, the executive must ask three questions key questions: Can I? Must I? Should I?

Can I? focuses on whether the agency has the legal authority to act, and if so, in what way? The public health agency's authority is based on the police power, which provides the authority for states to protect the public's welfare, safety, and health (*Jacobson v. Commonwealth of Massachusetts*, 1905). The parameters of authority are broad, but include constitutional safeguards for individual rights to liberty and due process.

Must I? asks whether there are legal requirements, including funding source directives, that mandate action and define how the agency must act? Usually, the agency has considerable discretion in deciding how to fulfill its obligation. Even if the agency must act, the activity need not address every aspect of the problem—selective action is permissible, absent bias or otherwise impermissible motives (*Youngberg v. Romeo*, 1982).

Should I? is a policy question requiring the executive to determine whether and how to exercise discretionary authority. Discretionary

authority must be used reasonably and impartially; never in an arbitrary and capricious manner. The optimal use of discretionary authority is challenging. If health officials make the wrong decision despite ambiguous or unavailable data, the public and media may harshly judge the process, the result, and the decision-makers (Jacobson et al., 2020).

Recognizing the need for simple, step-by-step guidance to aid public health officials faced with these difficult decisions, one of the authors created the Public Health Executive Decision Making Tool, which provides a template to support executive decision-making when confronting a public health threat (Chrysler et al., 2021). The tool does not provide an answer to the Should I? question; instead, it outlines a clear approach for analyzing a public health threat as it unfolds, and for documenting the decision-making process as follows.

1. **Assess the Situation:** Describe the facts as known and understood at the time. Focus on asking the right questions and not assuming the answers, and anticipate a quick evolution of facts and circumstances.
2. **Evaluate the Threat:** Determine the likelihood of the occurrence of each danger or threat based on current evidence. If the danger or threat occurs or continues, what are the potential consequences? During this step, it is important to consider the impact of these outcomes on different populations, especially the most vulnerable.
3. **Discuss Mitigation:** Consider the options and how the threat and/or danger can be addressed. What measures or mitigation might be used? What have others done in similar situations to mitigate impact or likelihood of reoccurrence? Consider the range of potential actions, mindful of the disparate effect on different populations
4. **Assess the Level of Certainty:** Weigh the potential harm of implementing measures or mitigation prematurely against delaying these actions. Before taking action, consider whether there are any other options; what resources are needed to execute and maintain the chosen course of action; how to know when no more intervention is needed; and how to measure success. Not acting is also a decision, not a default.
5. **Communicate:** From the beginning of the process, the executive must determine how much notice and information should be provided to the public. This requires careful deliberation and balance. Key considerations include whether notice will make a difference for those notified, what if any reasons there are for lack of transparency, and what is in the best interest of the public's health. Communicating the most accurate and up-to-date information is essential.

Legal Background

Most of the COVID-19 stay-at-home orders will be issued through a governor's authority to declare an emergency, which each state permits, or through similar actions taken at the local level. Governors and local officials may also rely on a state's public health code or other state laws to confront the pandemic. In this section, we outline those possibilities.

Based on previous work examining public health codes in eight states, the applicable laws will vary across states, but will be similar in structure, language, and intent (Jacobson et al., 2020). For convenience, we use Michigan law as a reasonably representative approach.

Emergency Declarations

In Michigan, the governor has a broad grant of authority to declare an emergency for 28 days under the Emergency Management Act of 1976 "...if he or she finds a disaster has occurred or the threat of a disaster exists". An epidemic constitutes a disaster. After 28 days, the governor must obtain legislative support to continue the emergency declaration (Emergency Management Act, 1976). Furthermore, Michigan's Emergency Powers of Governor Act provides similar authority without limits on the declaration's duration. Both Acts, and their cognates in other states, allow the governor to suspend state laws and rules as necessary to cope with the emergency, including stay-at-home or mask wearing requirements, or closing non-essential businesses.

Neither Act provides criteria or guidance for the governor's exercise of discretion in determining what constitutes a disaster. For good reason, these laws are designed to give the governor maximum flexibility to act quickly to avert or respond to a pandemic or other disaster. Likewise, federal emergency laws provide general authority without specific criteria or guidance.

Public Health Codes

Public health codes invest general authority at the state or local level to prevent disease, extend life, and promote the public health. To do so, health departments may "[a]dopt regulations to properly safeguard the public health and to prevent the spread of diseases and sources of contamination." More specifically, most codes recognize the need to take emergency action. In Michigan, for example, the appropriate authority follows "Local Health Department," 2020:

If the director or local health officer determines that control of an epidemic is necessary to protect the public health, the director or local health officer, by emergency order, may prohibit the gathering of people for any purpose and may establish procedures to be followed during the epidemic to insure continuation of essential public health services and enforcement of health laws. Emergency procedures shall not be limited to this code.

The Political and Judicial Contexts

Political Constraints. Despite the broad legal mandate, there are fundamental political, economic, and scientific constraints that any governor must consider in deciding when to issue or relax an emergency declaration. Governors face political and judicial constraints to stay-at-home orders or limiting business operations to those defined as essential. Every governor must balance the dangers of COVID-19 with the economic harm from lengthy stay-at-home orders and potential public health harms such as increased domestic violence or mental health concerns. Maintaining this

balance and communicating it to the public are challenging at a time when trust in governmental public health is low (Udow-Phillips & Lantz, 2020).

In states such as Michigan and Wisconsin, where the governor and state legislature represent different political parties and governing philosophies, political pressure is an inevitable feature of this process. Governors in both states have also faced contentious opposition and demonstrations from segments of the population opposed to any restraints on personal freedoms. More recently, opponents of emergency orders issued by these governors have begun protesting and threatening public health officials, forcing several to resign (Bosman, 2020).

Judicial Constraints. The ability to maintain stay-at-home orders and other restrictions on personal freedoms is not unlimited. So far, no court has yet overturned an emergency order or, though some courts have limited the scope of the orders (Wiley, 2020). Judicial tolerance is unlikely to last as litigation challenges to the restrictions multiply. For example, individual citizens and business owners continue to challenge emergency orders as infringing on fundamental rights, including First Amendment rights of free association and assembly, free speech, and freedom of religion. Litigants also raise Fourteenth Amendment challenges to stay-at-home orders based on due process and equal protection concerns and the right to travel. Other chapters in this Report provide greater detail on the litigation involving contact tracing, quarantine and isolation, privacy, and emergency measures.

In addition, disputes between state legislatures and governors have resulted in litigation. Courts in Wisconsin and Michigan, for instance, have rejected each governor’s attempt to extend the respective emergency declarations beyond the statutory maximum of 28 days. In both instances, the legislature successfully sued

the governor arguing that the traditional doctrines of separation of powers and checks and balances require legislative input into when and whether to relax the orders. However, Michigan Governor Whitmer was able to use Michigan’s Emergency Powers of the Governor Act to retain the emergency declaration. Suffice it to say that courts are likely to place an increasingly high burden on the governors to justify indefinite emergency declarations. In contrast, the governor of Georgia is attempting to enjoin the mayor of Atlanta’s mandatory mask-wearing order using separation of powers and state preemption arguments.

Executive Decision-Making: Covid-19

Unlike many other countries that swiftly responded to the emergence of COVID-19 by implementing national programs to curb the spread of the virus, the federal response has been largely absent after the initial March 13 declaration of a national state of emergency. Other than issuing sporadic, and often voluntary, guidance at the national level, the U.S. COVID-19 response has mostly been left to the states.

In COVID-19, the Can I and Must I questions have clear answers in most states—yes, the health officer can act, but there is no requirement to act. For the most part, the key question for a health officer is Should I in two very different contexts: should I recommend a robust stay-at-home order; should I recommend relaxing or terminating the order? No law requires a governor to declare an emergency. By definition, executive actions to declare a public health emergency are discretionary and fall in the category of Should I.

In this section, we focus on how eight states have used their legal authority to address the COVID-19 pandemic, along with recent case data (Figure 7.1). We examined the states’ legal responses

Figure 7.1

STATE	GOVERNOR PARTY	LEGISLATURE PARTY	AVG. NEW CASES / DAY
Alabama	Republican (Kay Ivey)	Republican	July 1: 679 July 16: 1729
Arizona	Republican (Doug Ducey)	Republican	July 1: 2750 July 16: 3249
Colorado	Democrat (Jared Polis)	Democrat	July 1: 212 July 16: 434
Florida	Republican (Ron DeSantis)	Republican	July 1: 3756 July 16: 11,147
Maine	Democrat (Janet T. Mills)	Democrat	July 1: 26 July 16: 17
Michigan	Democrat (Gretchen Whitmer)	Republican	July 1: 294 July 16: 623
Texas	Republican (Greg Abbott)	Republican	July 1: 4348 July 16: 9273
Wisconsin	Democrat (Tony Evers)	Republican	July 1: 330 July 16: 796

relative to the public health input the governors received. For each state, we examined the available emergency orders, the public health advice included in the orders, and consistency of the orders with available public health information. The full exhibit is on file with the authors.

The selected states examined in Figure 7.1 do not represent a random sample. Instead, they are a convenience sample based on geographic distribution, judicial activity, changing pandemic exposure, and political party control. Two states—Maine and Colorado—have Democratic governors and legislatures. In four states — Alabama, Arizona, Florida, and Texas — Republicans have full political control. Two states — Michigan and Wisconsin — have Democratic governors and Republican legislatures.

Analysis

Party Control. All of the sampled states issued stay-at-home orders in March 2020. After that, the states varied on when they relaxed the emergency orders and what other requirements accompanied reopening.

Four of the states with full Republican party control — Alabama, Arizona, Florida, and Texas — imposed no requirements in their initial emergency declarations. Instead, they relied on public health messages to encourage adherence to CDC guidelines regarding social distancing or wearing masks. In contrast, the other four states, two with full Democratic party control and two with a Democratic governor and Republican legislature, required wearing masks in public and banned gatherings of more than 10 persons. Each of these states opted for a phased reopening.

Role of Science. Although each of the initial emergency orders relied on public health data and collaboration with the state's health department, it is difficult to determine whether science actually guided decision-making for reopening or was subordinate to political and economic concerns. In most jurisdictions, science is vulnerable to elected officials' oversight. As the crisis evolved, several states either substantially relaxed their emergency declarations or implemented a phased approach to reopening, even as case numbers continued to rise.

Public health science played a prominent role in three states' emergency declarations: Maine, Colorado, and Wisconsin. In contrast to other states in our sample, these states have experienced only small increases in cases (Figure 7.1). Most likely, public health officials were involved in the other states' decision-making process.

Maine's commitment to following public health advice was incorporated into the emergency declaration. The director of the state's Department of Health and Human Services provided trends, metrics, and advice to "guide the timing pace and scope of any easing of [] restrictions."

In Colorado, the initial order noted that the state's approach was implemented after consultation "with public health officials" and is "based on models... proven effective." Similarly in Wisconsin, after

declaring a health emergency and directing the state's Department of Health Services (DHS) to lead the COVID-19 response, Wisconsin began a phased reopen subject to DHS's "assess[ment of] the most up-to-date data to determine when it is appropriate to progress to the next Phase."

Equity. The Emergency Declarations in our sample included minimal equity considerations or specific reference to vulnerable populations. For instance, Colorado requires essential workers and state employees to receive paid sick leave if they exhibit COVID-19 symptoms. Michigan exempted workers from the stay-at-home order who provide "food, shelter...for economically disadvantaged or otherwise needy individuals,... and people with disabilities," while Wisconsin exempted homeless individuals or unsafe residences (e.g., due to domestic violence).

Reopening. Despite issuing stay-at-home orders relatively early and, in most cases, waiting until May to begin reopening, four of the states surveyed are experiencing significant increases in cases — Alabama, Arizona, Florida, and Texas. In deciding to reopen, several states relied on their health department's advice. In Michigan, for instance, the governor stated, "In determining whether to maintain, intensify, or relax its restrictions, [the governor] will consider, among other things... data on COVID-19 infections and the disease's rate of spread." Some states, including Texas and Florida, have recently re-imposed restrictions as noted above because of spikes in COVID-19 cases.

After each state experienced a spike in COVID-19 cases, the orders were amended to: require masks for employees and ban gatherings of more than 25 persons (Alabama); close bars and allow local officials to require masks (Arizona); and close bars and ban gatherings of more than 100 persons (Texas). On July 2, the governor of Texas required wearing masks in public throughout most of the state.

Alabama began relaxing stay at home requirements May 21, but saw its numbers increasing by 32% compared to two weeks prior. Notably, industries and businesses were "strongly encouraged" but not required to follow the state Department of Public Health's guidance.


Arizona began reopening after data showed "continued progress in mitigating and limiting the spread of COVID-19 and sustaining adequate hospital capacity" according to the re-open order. Florida's re-open order on April 29th insisted that "data collected by the Florida Department of Health indicates the State has achieved several critical benchmarks in flattening the curve." Nonetheless, both states have seen a significant rise in cases since reopening.

Discussion

It should come as no surprise that states varied widely in their COVID-19 responses. Indeed, one might argue that this is a desirable feature of federalism where states can learn from alternative policy approaches. But it appears to be suboptimal in a pandemic that obviously ignores such boundaries and where a national approach would be preferable.

It would be nice to conclude that public health science has guided executive decision making in the COVID-19 pandemic, with politics as subordinate. In all likelihood, the reality is that the science is filtered through a very thick political lens. In short, governors making political decisions drove the process, not public health officials relying on the best available science.

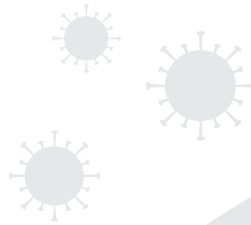
The fact that four states re-opened without any real requirements to address the threat of spreading or contracting the disease indicates the limits of public health science in shaping governors' decisions. Even so, it appears that science has been influential at two points – the initial emergency declarations, and deciding to retrench when states re-opened too quickly.

In fairness, the facts on the ground change so quickly that it is hard to blame governors and public health officials for struggling with COVID-19. Nevertheless, governors should be accountable if they either ignored the science or re-opened prematurely despite the science. Likewise, the American public needs to improve its compliance with recommendations for social distancing and mask-wearing. Without in any way understating those difficulties, governors could do a better job of communicating why social distancing and wearing a mask are essential for slowing the pandemic and mitigating its dreadful consequences. 

Recommendations for Action

State and local governments:

- Every emergency declaration should include the following information:
 - o Specific epidemiological data supporting the order;
 - o Specific requirements for social distancing and mask wearing;
 - o An explanation of why the order is needed;
 - o An explanation of why the order does not violate personal freedoms.
- Communications with the public should be transparent and provide:
 - o Current, accurate, and complete information;
 - o Clear, understandable, and effective recommendations/requirements to keep people safe;
 - o Reinforce that social-distancing and mask-wearing are the keys to eradicating COVID-19.
- Governors must protect public health officials from any threats to their health and safety.
- Governors should instruct public health officials to incorporate equity considerations and address the needs of vulnerable populations.
- States and localities should collect and analyze complete and accurate COVID-19 morbidity and mortality data on disparities by race, ethnicity, and age.



About the Authors

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References

- Adeline, S., Hanzhang Jin, C., Hurt, A., Wilburn, T., Wood, D., & Talbot, R. (2020). Tracking the Pandemic: Are Coronavirus Cases Rising or Falling in Your State? Retrieved July 22, 2020, from <https://www.npr.org/sections/health-shots/2020/03/16/816707182/map-tracking-the-spread-of-the-coronavirus-in-the-u-s>
- Bosman, J. (2020). Local Officials Fighting Crisis Now Endure Death Threats. *New York Times*. June 23, 2020, p. A10.
- Chrysler D., Gable L., Levin D., Jacobson P.D. (2021). Public Health Decision-Making: Responsibilities, Strategies, and Consequences. In M.N. Ransom & L.M. Valladares (Eds.), *Public Health Law: Concepts and Case Studies*, New York: Springer Publishing Company.
- Emergency Management Act, Michigan Compiled Laws §30.401 et seq. (1976).
- Jacobson v. Commonwealth of Massachusetts, 197 U.S. 11 (1905).
- Jacobson, P. D., Boufides, C. H., Chrysler, D., Bernstein, J., & Citrin, T. (2020). The Role of the Legal System in the Flint Water Crisis. *The Milbank Quarterly*, 98(2), 554-580.
- Multistate (2020). COVID-19 State and Local Policy Dashboard. Retrieved July 22, 2020, from <https://www.multistate.us/research/covid/public>
- Udow-Phillips, M., & Lantz, P. M. (2020). Trust in Public Health is Essential Amid the COVID-19 Pandemic. *Journal of Hospital Medicine*, DOI 10.12788/jhm.3474.
- Wiley, LF. (2020). The Emerging Law of Social Distancing. Draft manuscript on file with the authors.
- Youngberg v. Romeo, 457 U.S. 307 (1982).

Federalism in Pandemic Prevention and Response

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SUMMARY. Federal-state conflicts over business regulations, controls on personal movement, and financial support and coordination of supply chains have dominated headlines during the coronavirus pandemic. States hold the reins on most community mitigation measures (e.g., quarantine and isolation, physical distancing, and mask wearing), which may vary depending on local conditions. The federal government has authority to promulgate national guidelines and surveillance capabilities that states rely on when implementing, modifying, and easing community mitigation measures, but these guidelines have been inconsistent or absent. The federal government has provided limited financial support and coordination of supply chains to provide a foundation for state and local implementation of more targeted mitigation measures, which depend on widespread testing and disease surveillance. Federal-state conflicts have stymied efforts to ramp up and coordinate need-based distribution of resources for: 1) implementing widespread testing, tracing, and supported isolation and quarantine of individuals; 2) ensuring widespread availability of adequate personal protective equipment for health workers, other essential workers, and the general public; and 3) ensuring widespread access to therapeutics and vaccination based on equitable and public health-based criteria.

Introduction

In our federalist system, authority and responsibility for protecting the public's health is shared between the federal government, Tribal governments (addressed in Chapter 10), and the states, which typically delegate some of their authority to local governments. The federal government is limited to the exercise of powers enumerated in the Constitution. In contrast, states have plenary power to safeguard the public's health, safety, and welfare. Supreme Court precedents have interpreted limited federal powers—including powers to regulate interstate commerce and to spend for the general welfare—broadly, however, making it possible for Congress to encroach upon domains of traditional state and local authority. When the federal government acts, it can preempt state and local law. Similarly, state governments typically have broad authority to preempt local law.

Recognizing the substantial resources and interstate and international coordinating authority an effective public health crisis response requires, Congress has granted the federal administration a wide range of authorities that it can (but need not) use to address pandemics. Federal officials are authorized—but not obligated—to act: 1) to prevent the international or interstate spread of infection; and (2) in situations where state and local capacity is likely to be overwhelmed. These non-mandatory powers include providing critical supplies and financial resources. In some areas—including approval of laboratories, medical tests, vaccines, and drugs—Congress has preempted state authority. In other

areas—including travel restrictions, and isolation and quarantine of individuals—federal and state authority overlap. With so many overlapping authorities and responsibilities, it is unsurprising that inter-jurisdictional finger-pointing has marked nearly every major public health crisis in recent American history (Gostin & Wiley, 2016).

Federal-state conflicts over regulatory authorizations, business regulations, controls on personal movement, financial support, and coordination of supply chains have stymied the U.S. coronavirus response. Preventing a global pandemic from reaching the United States by stopping the spread of infection from international travelers and preventing community transmission from becoming widespread would have required more readily accessible testing than federal regulations, guidelines, and supply-chain coordination allowed. By the time community transmission was detected in multiple U.S. locations, targeted strategies relying on testing and isolating infected individuals and tracing and quarantining their contacts were not adequately funded to contain the spread of disease. As state and local governments entered the mitigation phase of the pandemic, most adopted restrictions on businesses and personal movement that exceeded the U.S. Centers for Disease Control and Prevention (CDC) (2020b) and White House (2020) guidelines. When the public became restless, state and local leaders eased restrictions more rapidly than federal guidelines recommended. At times, state and local efforts were coordinated regionally, but for the most part social distancing restrictions

varied considerably by jurisdiction. Throughout the crisis, federal financial support, legal protections (e.g., for employment, housing, and access to health care), and critical supply chain coordination have been needed, but inadequately provided, to: 1) implement widespread testing, tracing, and supported isolation and quarantine of individuals; 2) enable people and businesses to comply with social distancing while minimizing secondary harms; 3) ensure widespread availability of adequate personal protective equipment for health workers, other essential workers, and the general public; and 4) ensure widespread access to medical supplies and countermeasures based on equitable and public health-based criteria. The abdication of federal responsibility to support state and local efforts has exacerbated racial, socioeconomic, and geographic disparities in COVID-19 mortality and secondary impacts on housing, food, and economic security.

State and Federal Powers to Ensure Access to Testing

Testing is the foundation of modern pandemic prevention and response. If a virus is spread primarily by people who are symptomatic, isolation of the sick and quarantine of their contacts provides a highly effective and targeted approach to containing the spread of disease. The pre-symptomatic and asymptomatic spread of SARS-CoV-2 (the virus responsible for COVID-19) present greater challenges, requiring widespread and more or less continuous testing to screen the general population for infected cases so they can be isolated and their contacts can be traced, quarantined, and tested. In the absence of widespread testing, state and local governments have imposed restrictions on businesses and the general population.

A coordinated response to a novel virus requires suspension of Food and Drug Administration (FDA) regulations for approval of medical devices and laboratory certification (that would otherwise slow the release of test kits and processing of results, and which preempt state and local authority to approve new tests and other countermeasures) and an influx of federal funding for research, development, stockpiling, and distribution of critical supplies (Gostin & Wiley, 2016). The Defense Production Act authorizes the president to order manufacturers to produce these supplies and give priority to federal orders, but without adequate funding from Congress to pay for them, its usefulness is limited (see Chapter 23). CDC guidelines typically ensure uniform testing criteria, but if they are too rigid, they can impede local efforts to respond to dynamic conditions.

Federal efforts to ensure access to testing for SARS-CoV-2 have been largely unsuccessful (Shear et al., 2020). Upon Health and Human Services (HHS) Secretary Alex Azar's declaration of a public health emergency on January 30, 2020, federal agencies began to suspend FDA regulations and initiate public investments in research and production of test kits and other supplies. But a series of missteps led to a slow roll-out of testing. Secretary Azar decided to order CDC to develop a new test, rather than relying on tests the World Health Organization had deemed reliable. The initial CDC test kits were contaminated, stymying state and local containment efforts. Even as more reliable tests were pushed out, scarce supplies and laboratory capacity necessitated narrow CDC criteria that initially limited testing to symptomatic patients

with a history of travel to an affected area. In the last few days of February, shortly after CDC permitted state public health labs to begin processing tests and eased federal guidelines for who should be tested, community transmission was confirmed among several patients with no relevant travel history and no exposure to people known to have been infected (Shear et al., 2020). By that point, early efforts to contain the spread of infection from travelers to the general population had failed and the virus was already circulating widely in many parts of the United States. In March and April, with testing capacity still extremely limited, state and local leaders were left to make the only safe assumption: that community transmission was widespread throughout their jurisdictions and physical contacts among the general population must be drastically limited because anyone could be a silent carrier of infection. In the absence of a coordinated, federal approach, some governors have attempted to use interstate compacts to work together to secure supplies; others have been at odds with each other, using personal connections with suppliers and the president to obtain supplies for their own states while competing with others. On the whole, state efforts have been inadequate to shift to a more targeted pandemic mitigation or containment strategy.

The federal programs that have failed to ensure adequate access to testing are the same programs that are tasked with vaccine development and distribution. Unless supply chains, CDC guidelines which patients should be given priority for vaccination, and adequate funding for basic infrastructure—including PPE for the workers providing vaccinations and simple but scarce supplies like syringes, needles, and vials—can be secured by federal officials, the failures of early 2020 could be echoed in a massively failed vaccination campaign in 2021.

State and Federal Powers to Ensure Quarantine and Isolation of Individuals

While we wait for safe, effective, and widely distributed vaccines and other medical countermeasures, community mitigation strategies to separate the infected and exposed from the unexposed are our best defense. State and local governments have primary responsibility for quarantine and isolation of individuals within their states. Federal statutes give the director of the CDC authority to issue federal quarantine and isolation orders to stop the international or interstate spread of disease, but this authority has been used rarely in the modern era (Gostin & Wiley, 2016).

Although federal and state quarantine and isolation authorities overlap, they have not created major conflicts during the coronavirus pandemic. There were early clashes between federal authorities and local governments over where repatriated Americans would be permitted to disembark and stay for the duration of their quarantine, but these were settled through the use of military facilities and changes to CDC quarantine protocols (Chappell, 2020). Federal quarantine orders were issued to confine Americans the U.S. State Department repatriated from Wuhan, China and cruise ships (CDC, 2020a). There was at least one report of a local authority issuing its own quarantine order when one of these individuals sought to leave federal quarantine (Wigglesworth, 2020). States like New York and California were unable to follow through on contract tracing and management of people entering

from outside the United States, in part because of the antiquated system for getting information from federal authorities at the border to state officials responsible for quarantine (Myers et al., 2020). Overall, quarantine and isolation orders have not played a significant role in the pandemic because, by the time testing was more widely available, community transmission had become so widespread as to overwhelm federal, state, and local capacity to issue and enforce individual orders.

State and Federal Powers to Ensure Social Distancing and Face Covering Among the General Population

Federalism constraints were a significant barrier to the uniform, nationwide “lockdown” restrictions and face covering requirements some commentators argue would have ensured a more effective response to the coronavirus pandemic (Haffajee & Mello, 2020). At one point, the president asserted that social distancing restrictions were not within governors’ control because “[t]hey can’t do anything without approval of the president of the United States,” and “the authority of the president of the United States [over social distancing restrictions] is total” (White, 2020). In July, the president threatened to withhold federal funding from schools that did not fully return to in-person instruction. Legal scholars were quick to rebut his assertions of authority, clarifying that governors hold the reins on social distancing and face covering, subject to preemptive legislation by Congress (Gordon et al., 2020). Under the Constitution, federal restrictions on business operations and personal movement or requirements to wear face coverings must be adopted as a valid exercise of federal powers enumerated in the Constitution. Power to regulate interstate commerce and impose conditions on the acceptance of federal funds would probably be sufficient to permit Congress to adopt uniform social distancing restrictions and face covering requirements, but without a more specific delegation than the Public Health Service Act currently provides, the president does not have authority to interfere with state social distancing or face covering orders.

The federal government has authority to provide national guidelines and coordinate disease surveillance for states to rely on when implementing, modifying, and easing community mitigation measures, but CDC and the White House have exercised this authority in ways that have created inconsistency and even outright conflict (Wiley, 2020). For example, CDC’s community mitigation framework for COVID-19 was not widely publicized and its recommendations were contingent on data that was missing due to lack of widespread testing (CDC, 2020b). On March 16, the White House issued “15 Days to Slow the Spread,” which recommended that certain groups—people who feel ill, people who test positive for COVID-19 and their family members, and people who are older or who have serious underlying health conditions that put them at increased risk—should stay at home (White House, 2020). They also recommended that “[i]n states with evidence of community transmission, bars, restaurants, food courts, gyms, and other indoor and outdoor venues where groups of people congregate should be closed” (White House, 2020). By the end of March, when the White House extended its guidelines to “30 Days,” the majority of state and local governments had already implemented orders that went further than the White House recommended, ordering all

nonessential businesses to close and the general population to stay at home. Federal guidelines for easing social distancing restrictions were issued by the White House, not CDC. The guidelines were cautious but were nonetheless perceived as politically motivated by several governors, who announced that they would adopt their own plans. Some state and local officials adopted criteria for lifting social distancing restrictions only after testing, tracing, and isolation had been ramped up to provide an alternative mitigation strategy. When it became very clear that comprehensive federal support for testing and tracing was not forthcoming, and as the public began to question whether hospitals were truly at risk of becoming overwhelmed if restrictions were lifted, most governors lifted restrictions without regard to the cautious gating criteria they initially announced. Though their actions were inconsistent with official White House guidelines, they were cheered on by President Trump and his supporters.

Some state and local governments relied on informal compacts to coordinate their efforts to regulate businesses and restrict personal movement. Commentators suggested inter-jurisdictional coordination was critical to limit the incentive for residents to travel across jurisdictional lines for purchases or services not offered in their home jurisdiction. It may also have offered a modicum of political cover by minimizing the risk that any given official would be perceived as an outlier. On March 16, for example, the governors of New York, New Jersey, and Connecticut announced they would coordinate their prohibitions on gatherings and restrictions on bars, restaurants, gyms, movie theaters, and casinos other than those operated on tribal lands. The same day, several local health officers in the Bay Area of California issued nearly identical shelter in place orders, breaking the floodgates on “lockdown” style restrictions in the United States. Months later, some state and local governments coordinated their reopening strategies. For example, in April, governors of New York, New Jersey, Connecticut, Pennsylvania, Delaware, Rhode Island, and Massachusetts said they would launch a coordinated effort to reopen on their own terms. The governors of California, Washington, and Oregon made a similar joint announcement (White, 2020). But regional coordination gave way to varying reopening approaches in May. In late June, New York, Connecticut, and New Jersey coordinated their quarantines on travelers from states with rising case counts, including states like Florida that had previously issued quarantines on travelers from New York, Connecticut, and New Jersey.

Proponents of very strict social distancing and face covering orders expressed concern about lack of national uniformity (Haffajee & Mello, 2020), but it is unlikely they would have approved of a federally-controlled response that resulted in nationally uniform, but lighter, restrictions or preemption of state and local face covering mandates. Along with separation of powers constraints (discussed in the preceding Chapter), federalism constraints have allowed state and local governments to adopt and maintain health measures the president clearly opposes. Regardless of whether tighter or looser restrictions and mandates would have been a better approach, inconsistent messaging from federal, Tribal, and local leaders about the goals of social distancing, the level

of restrictions needed, and for how long may have eroded public cooperation and trust. Inconsistent federal messaging on face coverings certainly has.

Although social distancing strategies have focused primarily on restrictions on businesses and personal movement, supports to enable people to comply with public health recommendations are equally important. Federal efforts to provide financial support (e.g., stimulus payments and unemployment insurance), legal protections (e.g., paid family, medical, and quarantine leave), and accommodations (e.g., adapting federal school meal programs to allow pick-up service) to ensure that everyone is able to comply with social distancing restrictions and recommendations while minimizing secondary harms were spotty and inconsistent. Many state and local governments took steps to freeze evictions and utility shut-offs and provide nutrition support, but without more federal assistance, these efforts were largely stop-gaps.

State and Federal Powers to Support Other Strategies to Minimize Reliance on Social Distancing

State constitutional and statutory prohibitions on deficit spending and limited authority and capacity to coordinate international and national supply chains have hampered states' ability to implement less disruptive, more targeted strategies for mitigating the spread of the novel coronavirus. A scale-up of testing and tracing sufficient to safely ease restrictions would have required significantly more funding and coordination of complex international and national supply chains for scarce testing supplies. State and local governments have moved forward with easing social distancing restrictions in spite of not having adequate testing capacity to reliably detect and control outbreaks. Many state and local governments have relied on recommendations and mandates for the general population to wear face masks while looking to vaccination as a strategy for ending the pandemic some time in 2021. But even if a safe and effective vaccine is developed, its public health impact will depend on wide distribution. Distribution of vaccine supplies, if and when they become available, will depend on the same federal-state partnership that was intended to widely distribute testing supplies, medical equipment, and medicines. 🌐

Recommendations for Action

Federal government:

- Congress should use its appropriations power to:
 - o Provide more resources to state and local governments to implement supports, accommodations, and legal protections to enable individuals, families, employers, landlords, and local communities to comply with social distancing recommendations and restrictions. This financial support should not be conditioned on adopting a less cautious approach to social distancing restrictions (including school closures) or face covering requirements;
 - o Provide more funding to state and local governments to support testing and contact tracing.
- To strengthen capacity and reduce political interference with scientific analysis, Congress should urgently consider legislation to reorganize the CDC as an independent agency, on the model of the Federal Reserve.
- Congress should mandate and fund an effort to rebuild CDC's information infrastructure to ensure its disease surveillance reports and guidelines to governments, clinicians, businesses, private organizations, and individuals are accurate and free from political interference.
- To address shortages, bottlenecks, and interstate competition for scarce supplies, Congress should:
 - o Fund the purchase of PPE and test kits – including more accurate, less invasive tests that provide faster results – for distribution to state and local governments via the Strategic National Stockpile;
 - o Replace permissive language in the Public Health Services Act with mandatory language to direct the Department of Health and Human Services to support state and local efforts by acquiring and distributing supplies via the Strategic National Stockpile.
- Congress should amend the Public Health Service Act to add transparency and accountability mechanisms requiring the secretary of HHS and director of CDC to articulate the scientific basis for any guidance or orders issued pursuant to the authority provided by the Public Health Service Act to control the spread of communicable disease.

State governments:

- Every emergency declaration should include the following information:
 - o Specific epidemiological data supporting the order;
 - o Specific requirements for social distancing and mask wearing;
 - o An explanation of why the order is needed;
 - o An explanation of why the order does not violate personal freedoms.
- States should consider amending their constitutions and/or statutes imposing balanced budget requirements to permit deficit spending in times of crisis.
- In the absence of effective federal action, governors should take greater advantage of interstate compacts to coordinate acquisition and need-based distribution of supplies, and, eventually, vaccines.



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References

- Centers for Disease Control and Prevention (CDC)(2020a). CDC Issues Federal Quarantine Order to Repatriated U.S. Citizens at March Air Reserve Base. Retrieved July 24, 2020, from <https://www.cdc.gov/media/releases/2020/s0131-federal-quarantine-march-air-reserve-base.html>
- Centers for Disease Control and Prevention (2020b). Implementation of Mitigation Strategies for Communities with Local COVID-19 Transmission (March 12, 2020)(pdf on file with author).
- Chappell, B. (2020). Coronavirus: San Antonio Says Evacuees to Leave Quarantine after CDC Changes Protocol. *NPR*. Retrieved July 24, 2020, from <https://www.npr.org/sections/health-shots/2020/03/03/811582119/coronavirus-san-antonio-says-evacuees-will-leave-quarantine-after-a-cdc-change>
- Gordon, S. H., Huberfeld, N., & Jones, D. K. (2020). Insights: What Federalism Means for the US Response to Coronavirus Disease 2019. *Journal of the American Medical Association*. Retrieved July 24, 2020, from <https://jamanetwork.com/channels/health-forum/fullarticle/2766033>
- Gostin, L. O., & Wiley, L. F. (2016). *Public Health Law: Power, Duty, Restraint* (3d. ed.). Oakland, CA: University of California Press.
- Haffajee, R. L., & Mello, M. M. (2020). Thinking Globally, Acting Locally – The U.S. Response to Covid-19. *New England Journal of Medicine*, 382(22), e75(1)-e75(3).
- Myers, J. F., Snyder, R. E., Porse, C. C., Tecele, S., Lowenthal, P., Danforth, M. E., Powers, E., Kamali, A., Jain, S., Fritz, C. L., & Chai, S. J. (2020) Identification and Monitoring of International Travelers During the Initial Phase of an Outbreak of COVID-19 – California, February 3–March 17, 2020. *Morbidity and Mortality Weekly Report*, 69(19), 599–602.
- Shear, M. D., Goodnough, A., Kaplan, S., Fink, S., Thomas, K., & Weiland, N. (2020). The Lost Month: How a Failure to Test Blinded the U.S. to Covid-19. *New York Times*. Retrieved July 24, 2020, from <https://www.nytimes.com/2020/03/28/us/testing-coronavirus-pandemic.html>
- White House (2020). 15 Days to Stop the Spread. (March 16, 2020)(pdf on file with author).
- White, J. B. (2020) Trump Claims “Total Authority” Over State Decisions. *Politico*. Retrieved July 24, 2020, from <https://www.politico.com/states/california/story/2020/04/13/trump-claims-total-authority-over-state-decisions-1275506>
- Wigglesworth, A. (2020). American Under Coronavirus Quarantine after Trying to Leave California Base. *Los Angeles Times*. Retrieved July 24, 2020, from <https://www.latimes.com/california/story/2020-01-30/american-under-coronavirus-quarantine-after-trying-to-leave-california-base>
- Wiley, L. (2020). Public Health Law and Science in the Community Mitigation Strategy for Covid-19. *Journal of Law and Biosciences* (forthcoming).

Preemption, Public Health, and Equity in the Time of COVID-19

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SUMMARY. Preemption is a legal doctrine that allows a higher level of government to limit or eliminate the power of a lower level of government to regulate a specific issue. As governments seek to address the myriad health, social, and economic consequences of COVID-19, an effective response requires coordination between state and local governments. Unfortunately, for many localities, the misuse of state preemption over the last decade has increased state and local government friction and weakened or abolished local governments' ability to adopt the health- and equity-promoting policies necessary to respond to and recover from this crisis. The broad misuse of preemption has left localities without the legal authority and policy tools needed to respond to the pandemic. Existing state preemption of paid sick leave, municipal broadband, and equitable housing policies, for example, forced local governments to start from behind. Moreover, many state executive orders issued in response to COVID-19 outlawed local efforts to enact stronger policies to protect the health and wellbeing of communities. And, preemption in the time of COVID-19 has exacerbated the health and economic inequities affecting people of color, low-wage workers, and women. Conflict between state and local governments has cost lives, delayed effective responses, and created confusion that continues to undermine public health efforts. The new coronavirus pandemic has made it clear that the overwhelming majority of state preemption occurring today harms public health efforts and worsens health inequities. The crisis also has underscored the need to reform and rebalance the relationship between states and local governments.

Introduction

Preemption is a legal doctrine that allows a higher level of government to limit or eliminate the power of a lower level of government to regulate a specific issue. Under the Constitution, federal law takes precedence over state and local law. Similarly, if a local law conflicts with a state law, the state law generally takes precedence. Depending on the type of preemption, lower level governments may be prevented from passing any laws affecting a particular policy realm or from passing certain types of laws affecting that realm.

Historically, preemption was used to ensure uniform statewide regulation, protect against conflicts between state and local governments, and sometimes advance wellbeing and equity. Indeed, preemption is not inherently adversarial to public health, equity, or good governance. Targeted preemption has the power to promote fairness and equity when state or local governments enact harmful policies or when they fail to address systemic injustices (Carr et al., 2020). For example, states such as California and Oregon have preempted certain local laws to facilitate the production of more affordable housing.

However, in many state legislatures, preemption increasingly has been weaponized by well-organized anti-regulatory advocates to prevent local communities from enacting laws that could reduce inequities and enhance wellbeing. Rather than attempt to balance or integrate the interests of state and local governments, "new preemption" is characterized as "sweeping state laws that clearly, intentionally, extensively, and at times punitively bar local efforts to address a host of local problems" (Briffault, 2018).

New preemption is often driven by corporations, trade associations, and conservatives opposed to local regulation across a broad range of policies. These include policies related to minimum wage; commercial tobacco control; paid sick days; safe, stable, and affordable housing; and other laws that would directly benefit individuals such as low-wage workers, people of color, and women (Partnership for Working Families, 2019; Huizar & Lathrop, 2019; Policy Surveillance Program, 2019). The combined impact of existing preemption laws and preemption laws enacted in the context of COVID-19 has undermined local governments' ability to effectively and equitably respond to the health, social, and economic consequences of the pandemic.

Preemption has profoundly affected the public health response to COVID-19. Preemption laws that predated COVID-19 and those enacted during the crisis have made it more challenging for local governments to respond to and recover from COVID-19. Moreover, existing and newly enacted preemptive laws have made it more difficult to address the myriad inequities exposed and compounded by the pandemic.

Effects of Preemption Laws Enacted Prior to COVID-19

Since 2011, states have increasingly preempted local authority across a broad and growing range of economic, civil rights, health, and environmental issues. The consequence of this misuse of state preemption is that many local governments lack the authority to enact laws and policies that can reduce health inequities among underserved populations, such as people of color, low-wage workers, and women—the same communities disproportionately harmed by the health and economic effects of COVID-19 (Carr et al., 2020; APM Research Lab, 2020).

Widespread preemption during the years leading up to the pandemic meant that municipalities could not, for example, immediately adopt paid sick leave policies to cover health care and other frontline workers. State-level emergency paid sick leave policies were required in states such as Indiana, Michigan, and North Carolina, among others (A Better Balance, 2020). In some states, including Tennessee and Florida, advocates requested that their governors suspend paid sick leave preemption so local governments could do more to protect residents.

Similarly, the pandemic’s economic fallout worsened the existing housing crisis. Some local and state governments implemented eviction and foreclosure moratoria to keep residents from losing

Figure 9.1

POLICY AREAS AFFECTED BY NEW PREEMPTION	
New state preemption laws have restricted or eliminated local authority to protect public health and equity across a range of issues, including:	
Economic Policies Minimum wage, paid sick time, wage theft, local hire, pensions, fair scheduling	Public Health and Safety Laws Gun safety, tobacco and e-cigarette policies, food labeling, sugary drink regulation
Local Zoning and Affordable Housing Inclusionary zoning, rent control, source-of-income nondiscrimination, short-term rentals	Technology Broadband, 5G, self-driving vehicles
Civil Rights Antidiscrimination, sanctuary cities, immigration	Environmental Protection Factory farming, plastic bags, styrofoam, energy benchmarking, fracking

their homes. In some states, however, existing state preemption interfered with local governments’ ability to adopt such policies (Local Solutions Support Center, n.d.). In Wisconsin, the Tenant Resource Center explained that local governments are “prevented from doing so due to state preemption.” In contrast, California’s governor issued an executive order to suspend state preemption of certain types of local eviction protections.

With Americans forced to work, learn, and find medical treatment online, COVID-19 has also made fast, affordable, and reliable internet access essential. But in many states, preemption prohibits local governments from building or expanding access to municipal broadband—limitations that disproportionately hurt people of color, low income, and rural residents even before the pandemic (Community Networks, n.d.). Many states—including those with municipal broadband preemption—have acted to increase internet access and decrease costs. For example, the Nebraska Public Service Commission allocated funds to reimburse internet providers for providing service to low income families. Although some state action to expand broadband access may have been necessary irrespective of municipal broadband preemption, the inability of local governments to proactively address broadband access in the years leading up to the pandemic amplified the scope and urgency of state intervention.

Preemption in COVID-19 Executive Orders

Many state COVID-19 executive orders include express preemption that has hampered localities’ ability to protect their communities. State executive orders, including stay-at-home orders, have included three forms of preemption: floor, ceiling, and vacuum.

In some states, governors issued statewide stay-at-home orders but allowed local governments to implement additional restrictions based on local conditions. By establishing a **regulatory floor**, the executive orders did not prevent local governments from taking additional action to protect their residents. For example, Maryland’s governor lifted the state’s stay-at-home order but allowed for a flexible community-based approach, with local leaders making decisions regarding the timing of reopening. Prince George’s County, Montgomery County, and the City of Baltimore—home to the state’s largest Black and Latinx populations—opted to reopen more slowly.

Unfortunately, this collaborative approach is not the norm. In many states—Arizona, Florida, Georgia, Mississippi, South Carolina, Tennessee, Texas, and West Virginia, among others—the statewide stay-at-home orders established a **regulatory ceiling**. That is, the statewide orders prevented local governments from imposing stricter requirements than the state. For example, Arizona’s governor issued an executive order prohibiting any county, city, or town from issuing any order or regulation “restricting persons from leaving their home due to the COVID-19 public health emergency.” Similarly, the Texas attorney general warned officials in Austin, Dallas, and San Antonio to roll back “unlawful” local emergency orders that imposed stricter COVID-19 restrictions—and hinted that litigation would ensue if they did not.

Some states, such as Iowa, did not have any statewide stay-at-home orders in effect but still preempted local governments from issuing their own orders, creating a **regulatory vacuum**. For example, although the Iowa governor did not issue a statewide stay-at-home order, she and the state attorney general informed local officials that cities and counties lack the authority to close businesses or order people to stay at home.

As cases of COVID-19 surge, local governments have demanded the authority to respond with mandatory mask-wearing and other safety precautions, intensifying state-local government conflict. Governors in Oregon and Utah paused their reopening plans following steep increases in COVID-19 cases. In other hotspot states, however, governors initially refused to reimpose restrictions, frustrating local leaders who are preempted from enacting their own stay-at-home or physical distancing orders. Although the governors of Arizona, Florida, and Texas ultimately reversed state preemption of mandatory masking orders, at the same time, Nebraska's governor warned local governments they would not receive federal COVID-19 funds if they imposed masking or other local rules.

After California's governor issued a statewide mandatory masking order, several local law enforcement agencies announced they would not enforce the order. The mayor of Nevada City encouraged residents to defy the mandate to "prevent all of us from slipping down the nasty slope of tyranny." California localities that do not comply with minimum statewide health and safety standards will be ineligible for \$2.5 billion in state aid for local governments; however, unlike Nebraska, California does not intend to penalize localities that adopt more restrictive local orders. Governors in Pennsylvania, Illinois, North Carolina, and New Mexico, among other states, have also threatened to cut funding or take legal action against defiant localities.

Preemption and the Recovery

The misuse of state preemption is also undermining local governments' ability to effectively and equitably address long-term recovery from COVID-19. Areas of state and local conflict with the potential to impede recovery include preemption of local fiscal authority, worker safety laws, tenant and mortgage holder protections, emergency powers, stay-at-home orders, mandatory masking orders, sanctuary city protections, and elections.

For example, 48 states limit local fiscal authority to raise and spend revenue—known as tax and expenditure limits (TEs)—which will impede the economic recovery of localities with significant consequences for people who rely on local public health and safety, education, and other services (Policy Surveillance Program, 2019). As a result of these restrictions on tax revenues, cities are now cutting services when the community needs them most, laying off and furloughing employees, and mothballing capital projects, which has consequences for local employment, business contracts, and overall investment in the economy and community.

In the aftermath of the 2007–2008 housing crisis, moreover, local fiscal distress led to municipal bankruptcies, the imposition of state emergency managers, and other state takeovers of local

governments. As the water crisis in Flint, MI, attests, this kind of fallout can have dire consequences. Similar state interventions in the recovery ahead appear likely given the impact of the current downturn on local finances.

Housing, which has been a critical issue in acute responses to the COVID-19 emergency, is likely to remain an issue during recovery. Evictions and foreclosures disproportionately affect people of color, women, and low-wage workers. Although local governments are considering a range of tenant protections, such protections are among the many equitable housing policies preempted by states across the country, including rent regulation, inclusionary zoning, and source-of-income antidiscrimination (Local Solutions Support Center, n.d.).

Effects on Racial, Socioeconomic, and Other Preexisting Inequities

As local governments develop innovative solutions to advance health equity and improve health and wellbeing, preemption most often serves to impede such efforts (Carr et al., 2020). These impediments have substantial consequences generally and within the context of COVID-19 specifically.

For example, given the stark racial and socioeconomic disparities in health outcomes related to COVID-19—disparities directly attributable to racism and other forms of structural discrimination—state preemption of local preventive measures to reduce the spread of COVID-19, such as more protective local stay-at-home orders, is almost certain to worsen existing health inequities. This is particularly true when health status, including the existence of preexisting conditions that worsen negative outcomes related to COVID-19, is intimately tied to zip code, and can vary substantially over short distances.

State preemption laws affecting the social and structural determinants of health are also likely to create or worsen inequities. Governments at all levels have adopted emergency policies, including tenant protections, broadband access, paid sick and family leave, and economic supports like increased unemployment and nutrition assistance benefits. However, once the current pandemic subsidies and these temporary policies expire, widespread state preemption means that the same underserved populations unfairly harmed by COVID-19 will once again be unable to take action to protect their health and economic security. From an equity perspective, the misuse of state preemption to block local health and equity-promoting policies makes it harder for individuals and communities to care for themselves and their families. Indeed, because many states prohibit localities from enacting policies across a broad array of issues, millions of people—many of them from communities of color and low income communities—have been excluded from the opportunities and health benefits that those laws would provide (Partnership for Working Families, 2019; Huizar & Lathrop, 2019).

Similarly, state TEs that constrain the means by which local governments may raise revenues are also likely to undermine health and equity. The inability to raise revenue means that localities may lack the resources to provide the services and

supports necessary to counter the health and economic effects of COVID-19. Because COVID-19 has disproportionately affected underserved communities, these gaps in services and supports will further reinforce such inequities. Moreover, state TELs force local governments to turn to alternative forms of revenue generation, which often means fines and fees. Data show that people of color and residents who have low income are disproportionately affected by fees and fines for low-level offenses. “These fines and fees can affect credit scores, plunge families into debt, result in loss of a driver’s license, or lead to incarceration”—all outcomes that can negatively affect health (Watts & Michel, 2020).

Used appropriately, targeted preemption has the power to promote fairness and equity. For example, federal civil rights laws passed during the 1960s to counter government-sanctioned discrimination by states and localities were, in fact, preemption laws that established minimum nationwide protections. Those laws exemplify the use of preemption to advance equity and extend opportunity to people who were previously excluded (Carr et al., 2020).

In the COVID-19 context, targeted state preemption can help protect public health and advance health equity when local laws, government officials, or community opposition stand in the way of an effective response—by blocking testing centers or quarantine sites, for instance, or by lifting stay-at-home orders before state health officials determine it is safe to do so. Similarly, statewide stay-at-home orders can establish baseline protections for all residents while allowing local governments to impose additional restrictions that address variations in local conditions.

The COVID-19 emergency reminds us that the overwhelming majority of preemption laws sweeping the country represent a coordinated assault on the political power of communities of color, low income workers, and other marginalized groups. But it is critical to recognize that inequities result from decisions at all levels of government. As the country responds to and recovers from the COVID-19 pandemic, governments and public health decisionmakers must seek to repair and rebalance the relationship between state and local governments by combating the misuse of preemption while leveraging its potential to create and protect safety and opportunity for all. It is also critical to evaluate how state and federal preemption has affected both equitable responses to COVID-19 and ongoing recovery efforts, especially effects on underserved communities such as people of color, persons with low-incomes, and women.

Federal Preemption

Under the Constitution’s “Supremacy Clause,” federal law takes precedence over lower-level laws. The federal government has “limited powers,” meaning it only has those powers enumerated by the Constitution such as to tax, spend, and regulate interstate commerce. Despite these limitations, the federal government has the authority to make and enforce important laws related to public health and equity, including the ability to enact laws that preempt some or all state and local laws on particular issues. Indeed, while federal preemption has garnered less attention in recent years, it nevertheless remains a relevant consideration for responding to and recovering from the COVID-19 pandemic.

As with state preemption, federal preemption can sometimes advance public health and equity. The federal government, for example, exercised its authority under the Public Readiness and Emergency Preparedness (PREP) Act to preempt state and local laws restricting the ability of pharmacists to order and administer COVID-19 tests (U.S. Dept. of Health & Human Services, 2020). Despite operating as a constraint on state and local authority, such action is likely to support COVID-19 response efforts by increasing the availability of testing, particularly in underserved communities with limited access to health care services.

In other instances, federal preemption laws that predate COVID-19 and new proposals to preempt certain state and local laws have the potential to threaten effective and equitable response and recovery efforts. Proposals to take federal action to shield businesses from state laws imposing civil liability for harms resulting from COVID-19, for example, would remove incentives for businesses to proactively implement health and safety protections, as well as the ability to hold businesses accountable should they cause harm to customers or employees. In a similar way, federal preemption of state and local laws that limit mandatory arbitration clauses in employment contracts closes courts to workers and tends to favor employers. This may exacerbate health inequities given that many employees working in essential businesses are people of color, people with low incomes, and other individuals from underserved communities.

For additional information on various ways in which the federal government may constrain state and local authority, see Chapters 7 (restrictions imposed as a condition of federal funding), 8 (potential federal preemption of state and local stay-at-home orders), and 10 (Tribal authority). 🌟

Recommendations for Action

Federal government:

- Congress should adopt legislation prohibiting states from preempting local governments from building or expanding access to municipal broadband.
- Congress should not pass legislation shielding businesses from liability for failing to protect the health of customers and employees.
- Congress should amend the Federal Arbitration Act (FAA) to allow state and local laws restricting or prohibiting mandatory arbitration between employers/employees and businesses/consumers.
- The president should appoint judges receptive to legal theories protective against the misuse of state and federal preemption.

State governments:

- State governments should permanently remove state preemption of more protective local laws related to COVID-19 response (e.g., mask and physical distancing mandates), economic security (e.g., minimum wage, paid leave, employment protections), equitable housing (e.g., eviction moratoria, rent control, source-of-income antidiscrimination), municipal broadband, and civil rights (e.g., antidiscrimination laws, sanctuary cities).
 - Governors and other authorized officers should use their emergency powers to suspend preemptive laws preventing effective and equitable local responses.
 - Where necessary, state legislatures should amend state emergency laws to authorize the suspension of preemptive laws.
- Legislatures should repeal all state preemption laws that penalize localities or local officials that enact, enforce, or attempt to enact or enforce preempted or potentially preempted laws (e.g., laws subjecting localities and local officials to fines, civil liability, removal from office, and loss of funding).
- Legislatures, and voters in states that allow voter initiatives, should adopt structural reforms to strengthen home rule in alignment with the National League of Cities Principles of Home Rule for the 21st Century.
- Those responsible for appointing judges, and voters in states that elect judges, should select judges receptive to legal theories protective against the misuse of state preemption.

Local governments:

- Local governments and residents should support resolutions, lobby state lawmakers, and call for state executive action in support of local authority to enact more protective laws related to COVID-19 response (e.g., mask and physical distancing mandates), economic security (e.g., minimum wage, paid leave, employment protections), equitable housing (e.g., eviction moratoria, rent control, source-of-income antidiscrimination), municipal broadband, and civil rights (eg, antidiscrimination laws, sanctuary cities).
- Local governments and residents should advocate for state legislation or ballot measures expanding home rule authority in alignment with the National League of Cities Principles of Home Rule for the 21st Century.



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References

- A Better Balance (2020). Emergency Paid Sick Leave Tracker: State, City, and County Developments. Retrieved June 28, 2020, from <https://www.abetterbalance.org/resources/emergencysickleavetracker>
- APM Research Lab (2020). The Color of Coronavirus: COVID-19 Deaths By Race and Ethnicity in the U.S. Retrieved June 28, 2020, from <https://www.apmresearchlab.org/covid/deaths-by-race>
- Briffault, R. (2018). The Challenge of the New Preemption. *Stanford Law Review*, 70(6), 1995-2027.
- Carr, D., Adler, S., Winig, B. W., & Montez, J. K. (2020). Equity First: Conceptualizing a Normative Framework to Assess the Role of Preemption in Public Health. *The Milbank Quarterly*, 98(1), 131-149.
- Center for Public Health Law Research Policy Surveillance Program (2019). State Preemption Laws. Retrieved June 27, 2020, from <https://lawatlas.org/datasets/preemption-project>
- Community Networks (n.d.). Community Network Map. *National Employment Law Project*. Retrieved June 28, 2020, from <https://www.muninetworks.org/communitymap>
- Huizar, L., & Lathrop, Y. (2019). Fighting Wage Preemption: How Workers Have Lost Billions in Wages and How We Can Restore Local Democracy. *National Employment Law Project*. Retrieved July 7, 2020, from <https://www.nelp.org/publication/fighting-wage-preemption>
- Local Solutions Support Center. (n.d.). State Preemption of Local Equitable Housing Policies. Retrieved June 28, 2020, from <https://www.supportdemocracy.org/equitablehousing>
- National League of Cities (2020). Principles of Home Rule for the 21st Century. Retrieved July 7, 2020, from <https://www.nlc.org/resource/new-principles-of-home-rule>
- Partnership for Working Families (2019). For All of Us, By All of Us: Challenging State Interference to Advance Gender and Racial Justice. Retrieved July 8, 2020, from <https://www.forworkingfamilies.org/resources/publications/challenging-state-interference-advance-gender-and-racial>
- United States Department of Health and Human Services ("U.S. Dept. of Health & Human Services") (2020). Advisory Opinion 20-02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration Under the Act. May 19, 2020. Retrieved July 8, 2020, from <https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf>
- Watts, M. H., & Michel, K. H. (2020). Equitable Enforcement to Achieve Health Equity: An Introductory Guide for Policymakers and Practitioners. ChangeLab Solutions. Retrieved July 7, 2020, from <https://www.changelabsolutions.org/product/equitable-enforcement-achieve-health-equity>

Upholding Tribal Sovereignty and Promoting Tribal Public Health Capacity During the COVID-19

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SUMMARY. Tribes are sovereign nations with authorities and responsibilities over their land and people. This inherent sovereign authority includes the right to promote and protect the health and welfare of their communities. The COVID-19 pandemic has brought national attention to the health inequities experienced by American Indian and Alaska Native communities. The sovereign legal authority for Tribes to respond to this pandemic has received less attention. This Chapter describes some, but not all, of the urgent legal issues impacting Tribal response to the COVID-19 pandemic. It describes and identifies gaps in federal Indian health policies and highlights how Tribes have exercised their sovereignty to respond and promote resilience in the wake of COVID-19. It also provides examples of intergovernmental challenges. It highlights how ignorance of or animosity to federal Indian law has led non-Tribal governments to infringe on Tribal sovereign rights during the COVID-19 pandemic. It ends by providing a list of recommendations on how law can be better used to support Tribal responses as the pandemic unfolds.

Introduction

Tribes are sovereign nations with authorities and responsibilities over their land and people (Pevar, 2012). Tribes have been exercising this inherent authority since time immemorial. There are 574 federally-recognized Tribes within the United States. There are also dozens of state-recognized Tribes. Some Tribes have both state and federal recognition. Each Tribe's communities, histories, cultures, and laws are unique. Tribal authority includes protecting and promoting the health and welfare of their citizens (Hoss, 2019). Through the exercise of Tribal sovereignty, many Tribal communities have incorporated cultural practices into public health interventions, thus establishing health resiliencies. As sovereigns, Tribes maintain a government-to-government relationship with the United States, states, and other Tribes.

Based on treaties and federal law, the federal government has a legal obligation to provide health care to American Indians and Alaska Natives. Nonetheless, American Indians and Alaska Natives continue to experience health inequalities in areas such as heart disease, diabetes, and certain cancers. In light of such health inequalities, American Indian and Alaska Natives are at higher risk of serious illness if infected with COVID-19 and have been disproportionately burdened by the pandemic. As discussed below, inequities, memorialized in federal statutes and case law, have created structural barriers preventing comprehensive responses to COVID-19 in some Tribal communities. Tribal law, however, has

remained an effective tool in mitigating the failures in federal Indian health policy to respond to COVID-19.

This Chapter describes some, but not all, of the urgent legal issues impacting Tribal response to the COVID-19 pandemic. It first describes how federal Indian law impacts Tribal health systems, particularly in the context of infrastructure and funding. It also provides a brief overview of Tribal public health law and offers examples of the Tribal exercise of their public health authorities. It next identifies select issues that have arisen in the context of the state-Tribal coordination. It highlights how ignorance, or animosity of federal Indian law has led non-Tribal governments to infringe on Tribal sovereign rights during the COVID-19 pandemic. It ends by providing a list of recommendations on how law can be better used to support Tribal responses as the pandemic unfolds. This Chapter contemplates legal responses to support federally-recognized Tribal responses to the COVID-19 pandemic; however, much of the discussion outlined here may also be relevant to other Tribal governments.

In this Chapter, the Indigenous populations of what is now the United States will primarily be referred to as American Indian and Alaska Natives. The terms Native, Tribal, and Indian are also used. Federal law legally defines the Indigenous population of the United State as "Indian," so this term may be used when describing the law. The United States also colonized Native Hawaiian land,

which continues to be occupied today. Native Hawaiians are not considered Indians under federal law but are subject to other laws and policies not within the scope of this Chapter.

Tribes and the COVID-19 Pandemic

Several factors – e.g., health and socioeconomic disparities, lack of water, and food deserts – have made American Indians and Alaska Natives particularly vulnerable to the coronavirus pandemic. Consequently, Tribal communities suffer from some of the highest per capita COVID-19 infection rates in the country (IHS, 2020). To combat the pandemic in Indian country, the federal government has primarily focused on allocating funding to Tribes. In turn, Tribes are utilizing those funds to exercise their sovereignty to its fullest extent and to implement infectious disease control measures. Yet challenges remain, particularly in the context of intergovernmental coordination.

Federal Indian Law and Public Health

Following European colonization and the establishment of the United States, a unique framework of federal law developed to govern the legal relationships between Tribes, states, and the federal government (Fletcher, 2016). Federal law recognizes Tribal sovereignty: the right of Tribes to maintain jurisdiction of their land and people. It allows for Tribes to protect their people, cultures, and environment (Coffey & Tsosie, 2001).

Issues of jurisdictional conflicts involving Tribes are complex. In general, Tribal jurisdiction extends over their people and lands, and states generally do not have jurisdiction on Tribal lands. The federal government, however, can exercise concurrent jurisdiction on Tribal lands and can only diminish Tribal jurisdiction by explicit acts of Congress, disfavored in modern Tribal-U.S. relations.

Tribes may extend jurisdiction over nonmember conduct on Tribal lands in certain instances, including when such conduct “threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe” (“Montana v. United States,” 1981). Although Tribal authority over nonmember conduct is often challenged in court, Tribal authority to assert jurisdiction over nonmembers is at its strongest when responding to public health crises like COVID-19.

The federal government maintains a trust responsibility, a fiduciary and moral duty, towards Tribes based on treaties, case law, and legislation. The federal government must protect Tribal treaty rights, lands, and resources as well as consult with Tribes before taking action that impacts Tribes and their communities.

In exchange for ceded territories, the federal government is also obligated to provide health services to American Indians and Alaska Natives (Newton, 2012). Modern laws, such as the Indian Health Care Improvement Act, affirm this obligation and set forth federal policy to “ensure the highest possible health status for Indians and urban Indians and to provide all resources necessary to effect that policy.” Indian Health Services (IHS) is the federal agency primarily responsible for delivery of these services and does so either directly through its own facilities and programs, or indirectly through Tribally-operated facilities and programs authorized under

P.L. 93-638. IHS also provides funding to over 40 urban Indian health programs to service American Indians and Alaska Natives living in urban areas. It supports Tribal Epidemiology Centers, which, in partnership with Tribes, provide public health surveillance and other support.

Persistent Failure of the Federal Government to Honor Its Treaty Obligations. The health of American Indians and Alaska Natives is intrinsically tied to federal law and reliant upon the federal government fulfilling its treaty obligations and trust responsibilities. The federal government has largely reneged on this responsibility as the federal Indian health system has been overburdened and underfunded for decades. Due to funding shortfalls, IHS expenditures per capita are well below other federal health care programs and cover only a fraction of American Indian and Alaska Native health care needs (Broken Promises, 2018). According to the 2019 National Tribal Budget Formation Workgroup’s Recommendation on the IHS Fiscal Year 2021 Budget, an estimated \$32 billion would be required to fully fund IHS.

Even in areas where the federal government has made progress in better supporting Indian health programming, there remains substantial room for improvement. For example, recent amendments to the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988 (Stafford Act) finally allowed Tribes to directly request national emergency and disaster relief resources from the federal government in lieu of funneling such requests through state governors; but, the Stafford Act still requires cost sharing from Tribal governments receiving funds.

As another example, the federal government initiated the Special Diabetes Program for Indians to reduce instances of diabetes in Indian country. Importantly, individuals with diabetes are likely to have worse COVID-19-related outcomes and American Indians and Alaska Natives have long suffered from diabetes at higher rates. Despite being a highly successful program, funding has repeatedly been on the brink of lapsing, avoided only by temporary funding fixes instead of permanent reauthorization. In both emergency assistance and diabetes funding, the federal government is already obligated to provide such health programming under its treaty and trust obligations.

Aside from health care services, the federal trust obligation plays a role in other areas such as criminal justice and public safety, education, housing, and economic development. The federal response to address disparities and meet its trust responsibility in these areas has been lacking as well. In light of these unfulfilled promises, many Tribal communities suffer from a broken infrastructure and lack basic utilities such as running water and electricity. Housing shortages are also rampant, resulting in overcrowded homes. Access to broadband internet is limited, making it difficult for Tribal governments and members to function remotely (see Chapter 30). All of these factors hinder the ability of Tribes to safeguard against COVID-19.

Furthermore, the federal government’s response to Tribal requests for help during the pandemic has been delayed and often grossly deficient. For example, the Sault Ste. Marie Tribe of Chippewa

Indians, a Tribe with over 40,000 members, received only two test kits (Hilleary, 2020); and instead of receiving personal protective equipment to fight COVID-19, the Seattle Indian Health Board was sent body bags (SIHB Staff, 2020). Additionally, while state and local governments have accessed the Strategic National Stockpile (SNS) for critical medical supplies, Tribal access has been limited and not guaranteed.

CARES Act Funding. Of the COVID-19 legislative packages passed, the Coronavirus Aid, Relief, and Economic Security (CARES) Act has been the most significant for Tribes. The original bill included few provisions for Tribal communities, prompting a united effort by Tribal advocates to ensure their voices were heard. The final bill included financial assistance to Tribes and Tribal business entities, funding for federal agencies with set-asides for Tribes and Tribal services, and increased funding for programs in which Tribes and Tribal members can participate (e.g., Child Care and Development Block Grants to provide child care assistance and Fishery Relief to alleviate fishery-related economic losses and other negative impacts). The CARES Act created a Coronavirus Relief Fund of \$150 billion, including \$8 billion in direct assistance for Tribal governments. The IHS also received \$1.032 billion to fund IHS, Tribal, and Urban Indian Organization programs, as well as electronic health record stabilization and support.

While the CARES Act provides much-needed resources to Tribes, the funding comes with restrictions on how and when the funds can be used, limiting Tribal responses. It also authorized funding to non-government entities, such as Alaska Native Health Corporations, thus reducing the amount of money provided directly to Tribes.

Tribal Public Health Law

Tribal sovereignty includes the inherent authority for Tribes to promulgate their own laws and regulations. This authority includes the ability to promote public health in their communities and is further reinforced in Tribal constitutions, Tribal codes, and Tribal policies. Some Tribes expressly reference health protection and promotion as an authority of the Tribal government. Some Tribal codes establish health and emergency management agencies, designate health directors, establish emergency authorities, and require the development of health policies. Regardless of whether such provisions exist in a Tribal code or not, Tribes maintain authority to protect public health as an inherent component of their sovereignty. Codes and other policies, however, can operationalize services and programs to promote public health.

Tribal Infectious Disease Control Measures. As COVID-19 cases continued to increase in Indian country, pressure was placed on Tribal facilities to respond and meet the growing needs of their communities. While these facilities and programs play an important role in providing essential care and services, Tribal governments remain the proper entity responsible for enacting the public health orders and measures in Indian country.

Many existing Tribal health codes and policies provide Tribal government authority to isolate, quarantine, and contact trace members, in addition to other infectious disease control. Once

COVID-19 reached Tribal communities, many Tribal governments began to execute measures to curb its rise, including curfew, quarantine, social distancing, and mask requirements. The Navajo Nation, for example, implemented one of the most restrictive stay-at-home orders, imposing a long-running 57-hour weekend curfew. In the wake of COVID-19, some Tribes adopted more comprehensive policies to ensure that such measures were conducted in a more culturally appropriate way and discussed within traditional learnings and stories, as the Navajo Nation did. The American Indian Health Commission of Washington discusses the importance culturally appropriate responses in its Model Tribal Isolation and Quarantine Plan.

It is critical that federal, state, and local governments respect Tribal authority and jurisdiction to undertake public health measures. The exercise of Tribal legislative and regulatory authority, however, can raise issues of jurisdiction when enforcing them against nonmembers on Tribal lands. This issue is discussed in the subsequent section.

Intergovernmental Coordination

State-Tribal Jurisdiction. As outlined above, federal law outlines jurisdictional relationships between Tribes, states, and the federal government. Responding to public health crises like COVID-19 often implicates jurisdictional issues, particularly when neighboring governments are unfamiliar with federal Indian law.

The conflict between the Oglala Sioux Tribe and the state of South Dakota offers a timely example. In April 2020, the Oglala Sioux Tribe implemented a Tribal Border Management Plan that established checkpoints alongside two Tribal highways to assess the potential COVID-19 risk of travelers entering the Tribe's reservation. At checkpoints, travelers were asked about any COVID-19-related symptoms and whether they were conducting an essential business. The Cheyenne River Sioux Tribe established similar checkpoints.

The state of South Dakota, led by Governor Kristi Noem, opposed these checkpoints, arguing the Tribes were acting outside of their jurisdiction. This argument, however, runs against Tribal sovereignty and established principles of federal Indian law. States do not have jurisdiction within the boundaries of the Tribal lands, including the roads and highways crossing such lands. This legal principle was further recognized by the Bureau of Indian Affairs in an April 8, 2020 letter contemplating such checkpoints to respond to the COVID-19 crisis.

The state continued to oppose the Tribal checkpoints, even appealing to President Trump. Tribal representatives responded to state and media inquiries on the topic, thus taking their time away from other urgent response efforts. Despite threats of litigation from the state, South Dakota did not sue for the removal of Tribal checkpoints.


Inconsistent response measures across jurisdictions can also create challenges for Tribal governments. In their COVID-19 response, some Tribes implemented stay-at-home orders and other requirements on Tribal lands to curb cases. When neighboring

states and local governments fail to implement similar measures, it puts Tribal members, who may live or work outside of Tribal lands, at risk as well. Additionally, nonmember failure to comply with Tribal protective measures on Tribal lands puts the entire community at risk. From a public health standpoint, it seems clear that an individual infected with COVID-19 is a direct threat to the health or welfare of the Tribe, and therefore, such Tribal orders are valid and enforceable against members and nonmembers alike.

Intergovernmental communication and coordination can support more comprehensive and consistent prevention measures. Legal tools can be used to facilitate intergovernmental cooperation between Tribes and states. For example, mutual aid agreements or memoranda of understanding can be reached to respond to public health emergencies. Such documents can allow for resource sharing for contact tracing, isolation and quarantine activities, and personnel. They can also facilitate and require data sharing and can establish protocol for intergovernmental communication. Tribes should consult with their counsel to ensure that such documents are written in a way that do not compromise Tribal sovereignty.

Public Health Data Access. Public health data collection and surveillance are essential to public health practice and health emergency responses. Data has been cited as a leading challenge in the Navajo Nation's COVID-19 response, with officials believing that case and death counts have been underreported (Whitford, 2020).

In practice, Tribes have experienced inequities and other challenges in securing health data. Despite being governmental public health authorities, some governments and entities refuse to provide Tribes access to health data, citing privacy concerns. Additionally, data is often housed in different software across organizations, making it difficult, costly, or even impossible to integrate data into existing systems. American Indians and Alaska Natives are also subject to persistent racial misidentification by health care providers, leading to erasure of this population in policymaking at the federal, state, and local levels. This further compromises the ability of Tribes to craft a targeted response. Recent reporting found that American Indians and Alaska Natives are regularly left out of state demographic data classifications in COVID-19 surveillance, being characterized merely as “other” (Nagle, 2020).

Given the long history of government and researcher misuse of health data pertaining to American Indians and Alaska Natives, data usage and ownership is also a priority consideration for Tribal governments. Inaccurate or misleading data presentations can negatively impact policy and funding decisions, and perpetuate stigma and stereotypes that compromise effective public health programming. 

Recommendations for Action

Tribal governments:

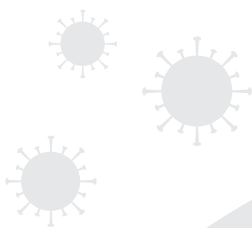
- Continue to incorporate culturally appropriate mechanisms when using legal measures to contain the spread of COVID-19.
- If not already in place, consider passing a public health code that contemplates issues of health communications, quarantine and isolation, incident command systems, and a point of contact for public health issues for the Tribe.
- Consider entering into data sharing and mutual aid agreements or memoranda of understanding with neighboring jurisdictions, Tribal Epi Centers, and clinics to support and coordinate COVID-19 responses. Work with Tribal counsel to ensure that Tribal sovereign rights are not compromised in such agreements.

Federal government:

- Honor trust responsibility and consultation requirements as outlined by federal law.
- Provide funding mechanisms directly to Tribes at rates equal to or higher than those provided to states and local governments. Do not delay in the distribution of such funds. Do not use Tribal-serving organizations or entities as proxies for funding directly to Tribes.
- Require state and local government recipients of COVID-19 grants and cooperative agreements to meaningfully consult with Tribes in the area in the disbursement of funds or services. Require documentation of such consultation as a condition of funding.
- Sufficiently fund IHS, Tribal health facilities, and Urban Indian health centers.
- Provide additional funding for other Indian health programs. For example, permanently reauthorize the Special Diabetes Program for Indians. Alternatively, provide a long-term reauthorization of SDPI.

State and local governments:

- If not already in place, enact law that requires consultation with Tribes in the area if the state or local government is making law or policy that impacts the Tribe.
- Work with Tribal governments to enter into data sharing and mutual aid agreements or memoranda of understanding. Do not require Tribes to waive sovereign rights as a condition of these agreements.
- Share COVID-19-related public health data with Tribes.
- Respect Tribal authority and jurisdiction to promote the health and welfare of their communities and to implement COVID-19 response measures on their lands, including curfews, checkpoints, mask wearing, and other requirements.



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References

- Coffey, W., & Tsosie, R. (2001). Rethinking the Tribal Sovereignty Doctrine: Cultural Sovereignty and the Collective Future of Indian Nations. *Stanford Law and Policy Review*, 12(2), 191-221.
- Indian Health Service (IHS)(2020). Coronavirus (COVID-19). Retrieved July 23, 2020 from <https://www.ihs.gov/coronavirus/>
- Fletcher, M. L. M. (2016). *Federal Indian Law*. St. Paul, MN: West.
- Hilleary, C. (2020). Native American Tribes Face Critical Shortages of COVID-19 Test Kits, Protective Gear. *Voice of America*. Retrieved July 10, 2020, from <https://www.voanews.com/science-health/coronavirus-outbreak/native-american-tribes-face-critical-shortages-covid-19-test>
- Hoss, A. (2019). A Framework for Tribal Public Health Law. *Nevada Law Journal*, 20(1), 113-144.
- Montana v. United States, 450 U.S. 544 (1981).
- Nagle, R. (2020). Native Americans Being Left Out of US Coronavirus Data and Labelled as 'Other.' *The Guardian*. Retrieved July 10, 2020, from <https://www.theguardian.com/us-news/2020/apr/24/us-native-americans-left-out-coronavirus-data>
- Newton, N. J. et. al. (Eds.)(2012). *Cohen's Handbook of Federal Indian Law*. Albuquerque, NM: LexisNexis.
- Pevar, S. L. (2012). *The Rights of Indians and Tribes*. New York, NY: Oxford University Press.
- Seattle Indian Health Board (SIHB) Staff (2020). Affirming Our Gratitude and Clarifying Our Request for Supplies. Retrieved July 10, 2020, from <https://www.sihb.org/2020/05/affirming-our-gratitude-and-clarifying-our-request-for-supplies/>
- U.S. Commission on Civil Rights (2018). *Broken Promises: Continuing Federal Funding Shortfall for Natives Americans*. Retrieved August 2, 2020, from <https://www.usccr.gov/pubs/2018/12-20-Broken-Promises.pdf>
- Whitford, E. (2020). Navajo Virus Case Bump Highlights Data Challenges. *Law360*. Retrieved July 10, 2020, from <https://www.law360.com/articles/1273585/navajo-virus-case-bump-highlights-data-challenges>

U.S. Withdrawal From the World Health Organization: Unconstitutional and Unhealthy

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SUMMARY. On May 29, 2020, during the same week that U.S. deaths from COVID-19 topped 100,000, President Trump announced that the United States would end relations with the World Health Organization (WHO). In the beginning of July, the administration formally notified the United Nations of the decision to withdraw. Withdrawing the United States from the WHO would threaten both national and global health interests. The loss of U.S. funding would derail WHO's ability to detect and respond to emergencies like COVID-19, and could reverse hard-won progress in combatting infectious and non-communicable diseases, and addressing the social determinants of health globally. The United States also would cede its position as a global health leader, curtailing its ability to engage in global health diplomacy. Yet President Trump's apparent attempt to unilaterally withdraw the United States from the WHO raises major constitutional implications, and Congress must not let the move go unchallenged. As the United States entered the WHO through a joint congressional resolution, the same process should be required to exit the WHO. That joint resolution also imposes withdrawal requirements of one year's notice and full payment of dues for that year. These two conditions indicate Congress' intent to maintain a role in any decision to vacate the WHO. Congress must now step into that role and prevent the president from ending WHO membership and funding.

Introduction

President Trump's announcement that the United States would immediately terminate relations with and stop funding the World Health Organization (WHO), even as the agency leads the global response to a massive and still growing pandemic, is not only a shocking abrogation of U.S. global health leadership, already diminished by a meager response to COVID-19 globally. It is also an unconstitutional assertion of presidential power.

The United States has been a member of the WHO since its founding in 1948, and had championed its establishment to help countries address threats including malaria, tuberculosis, venereal disease, children's and women's health, nutrition, and environmental sanitation. Since then, U.S. presidential administrations have consistently supported the WHO. U.S. voluntary and mandatory funding contributions have established the United States as a leading ally to WHO in addressing threats like HIV, Ebola, and polio.

Yet now, for the first time in more than 70 years and in the midst of a devastating pandemic, the U.S. role as a WHO member and global health leader are at stake. Congress must not acquiesce to an

action that would not only be a major blow to global health, but also to the balance of power and the credibility of U.S. commitments enshrined in treaties, legally binding agreements between nations. By terminating obligations to the WHO, the United States would also be sidestepping its commitments to global health security.

The Health Consequences of a U.S. Withdrawal From WHO

Exiting from the WHO places U.S. health and national security interests at risk. COVID-19 has proven how the zoonotic leap of a single virus anywhere in the world can result in health and economic catastrophe in the United States. Once outside the WHO, the United States would no longer be a part of the WHO's global system for sharing critical outbreak and vaccine data, potentially slowing the United States' ability to recover from COVID-19, and to react to future pandemics.

The rest of the world would be at heightened risk, too. As the United States is a major funder this year of WHO's health emergency response capacities, resources for testing and contact tracing, building health workforces, and developing vaccines would be lost with U.S. withdrawal (WHO, 2020). Second or third waves of

COVID-19 cases could repeatedly overwhelm health care systems and result in far more lives lost. Beyond COVID-19, the WHO would have reduced capacity to detect and control future outbreaks without U.S. support, marking a new era of pandemic risk.

A number of other WHO programs would suffer enormously under U.S. withdrawal, especially as many global health resources have been redirected to fight COVID-19. Historically, the United States has served as a global health leader and the largest WHO donor (providing about 15% of its budget, or \$450 million annually) (WHO, 2020). The United States has helped fund such initiatives as polio eradication, child nutrition, vaccines, HIV/AIDS, malaria, and tuberculosis. Pulling funding could reverse hard-won progress. For example, efforts to eradicate polio over the last two decades have reduced global cases by 99.9%, but loss of U.S. funding could potentially allow annual global polio cases to jump from a few hundred to 200,000 within a decade.

Though the United States may attempt to remain a global health leader by rerouting funding directly to countries, or through global public-private partnerships, it will have far less impact without WHO expertise and global reach. Even the President's Emergency Plan for AIDS Relief, the U.S.'s signature achievement in responding to HIV/AIDS, has relied on WHO to deliver health messages, ensure quality medications, and set health workforce standards. As U.S. global health funding and leadership falters, the United States will lose capacity to engage in global health diplomacy.

WHO is working worldwide to achieve its triple billion goal: to ensure that a billion more people have universal health coverage, that a billion more people are protected from health emergencies, and that a billion more people enjoy better health and well-being. The COVID-19 pandemic is a major obstacle toward achieving these goals, and the world's most vulnerable populations have faced the biggest threats of the pandemic. Refugees and migrants, as well as impoverished persons living in crowded, unsanitary conditions, often lack access to health care and other resources that WHO is working to ensure. COVID-19 exemplifies why more resilient health systems are so badly needed, and should stimulate countries' future investments in global health. Yet at this moment when global solidarity is necessary to overcome the common enemy of COVID-19, the loss of U.S. funding and support for WHO places the world at far greater risk.

Presidential Authority to Withdraw From WHO

The debate about the president's authority to withdraw from treaties stems from the U.S. Constitution's silence on the matter, stipulating that two-thirds of Senators must agree to ratify a treaty, but stating nothing on withdrawal. Over the years, even how a treaty is defined and adopted has shifted away from the Constitution's apparent hard-and-fast rule, with many international agreements adopted through other procedures. The WHO Constitution was adopted through a joint congressional resolution, akin to regular legislation. Critically, foreign relations is an area where, even apart from their joint role in treaty-making, Congress and the president both have constitutional powers, including the former's power to declare war, regulate the armed forces, and regulate commerce among nations, and the latter's role as commander-in-chief and authority to appoint and receive ambassadors.

A common misperception is that the president has the authority to unilaterally withdraw from treaties, due to a history of such actions going unchallenged by Congress over the past century, and the 1979 Supreme Court case, *Goldwater v. Carter* (Bradley et al., 2017; *Goldwater v. Carter*, 1979). In that case, the Court, in a result agreed to by six justices, required the lower court to dismiss a challenge to President Carter's unilateral decision to terminate a mutual defense treaty with Taiwan. Four of the justices would have dismissed the case as a non-justiciable political question. In his concurrence, Justice Powell agreed with the result, but expressly rejected the notion that the Court had no role: "the suggestion that this case presents a political question is incompatible with this Court's willingness on previous occasions to decide whether one branch of our Government has impinged upon the power of another" (*Goldwater v. Carter*, 1979).

Meanwhile, not a single justice stated that the Constitution gives the president a general power to unilaterally withdraw from treaties. The plurality opinion of four justices expressly recognized that different procedures could be appropriate for different treaties. Two dissenters would have heard the case. And in a separate dissent, Justice Brennan, would have upheld the president's power to terminate the treaty based on the narrow grounds that President Carter's decision to terminate the treaty was directly linked to the "President's well-established authority to recognize, and withdraw recognition from, foreign governments" (*Goldwater v. Carter*, 1979). Yet even if the president has the established authority to unilaterally withdraw recognition from a foreign government, this is not equivalent to withdrawing from a multilateral treaty with 194 parties on an international organization devoted to global health.

As a matter of constitutional design, it is highly questionable whether the president may unilaterally withdraw from a treaty that the United States enters into with congressional action. The best understanding of treaty withdrawal under the U.S. Constitution is a "mirror principle," that the same process for entering the treaty is necessary for withdrawing from it (Koh, 2018). And President Harry Truman did not enter the United States into WHO by his action alone. Rather, the United States joined only after a joint congressional resolution, signed into law by President Truman in 1948, that approved U.S. entrance into WHO — a congressional-executive agreement. Accordingly, under this principle, only another resolution from both houses of Congress, signed by the President, could withdraw the United States from WHO.

Even without adopting the mirror principle, the specifics of the 1948 joint resolution militate against unilateral withdrawal. Since WHO's Constitution is silent on whether or how member states could withdraw from the organization, the joint resolution specified that the United States could withdraw from WHO, but only under two conditions (Constitution of the World Health Organization, 1948). First, the United States would have to provide WHO one year's notice, and second, the United States would have to meet its financial obligations for WHO's current fiscal year.

The one-year notice condition also indicates that in this domain of shared and contested authority, foreign relations, withdrawing from WHO is not the type of action that is filled by the president's

role as the nation's chief diplomat, which may require — as the circuit court recognized in *Goldwater v. Carter* — “immediate action” (*Goldwater v. Carter*, 1979). Congress constrained the president such that the United States cannot immediately withdraw from WHO. Immediate action, in this case, is not an option.

The requirement on meeting U.S. financial obligations for WHO's current fiscal year is one that necessitates congressional action, with Congress's sole power to authorize and appropriate funding. Congress, therefore, clearly intended to retain its role in any decision to withdraw from WHO. And as Supreme Court Justice Robert Jackson explained in his classic concurring opinion in *Youngstown Sheet & Tube Co. v. Sawyer*, “When the President takes measures incompatible with the expressed or implied will of Congress, his power is at its lowest ebb” (*Youngstown Sheet & Tube Co. v. Sawyer*, 1952). Here, the president would be acting against the implied will of Congress.

Notably, this was not the case with respect to the treaty at issue in *Goldwater v. Carter*. When the Senate approved that treaty, it extensively debated — and ultimately did not vote on — a resolution to require the Senate to approve treaty termination (Hurd, 2018). Unlike Congress's approval of U.S. entrance into the WHO, then, the Senate in that case was on record of at least implicitly acceding unilateral termination authority to the president.

President Trump has himself, without challenge from Congress (thus far), withdrawn or begun the process of withdrawing from two arms control treaties, the Intermediate Nuclear Forces (INF) Treaty, and the Open Skies Treaty. In approving the INF Treaty, the Senate was silent on the withdrawal process (Pompeo, 2019). However, in the 2019 National Defense Authorization Act, Congress stated that the United States was “legally entitled to suspend the operation of the INF Treaty,” on the belief that Russia had materially breached the treaty, prospectively endorsing administration action to step back from the treaty's operation. This express statement on suspension but not withdrawal could be read that Congress supported suspension but opposed withdrawal. However, Congress neither challenged the president legislatively or in court.

Anticipating the possibility of the president seeking to withdraw from the Open Skies Treaty, Congress set procedural requirements in recent defense legislation for the Secretaries of Defense and State to notify Congress of its intent to withdraw before notifying other treaty parties (United States Participation in Open Skies Treaty, 2019). The administration failed to comply with these requirements. Still, unlike for exiting the WHO treaty, Congress did not suggest a role for itself in approving the withdrawal itself; it merely required prior notification, and the Senate had been silent on its role in withdrawal when ratifying the treaty (U.S. Dept. of Defense, 2020).

The most significant court case since *Goldwater v. Carter* on presidential unilateral treaty withdrawal authority was a DC District Court case, *Kucinich v. Bush*, where 32 members of Congress challenged President George W. Bush's unilateral authority to withdraw from the Anti-Ballistic Missile (ABM) Treaty with Russia (*Kucinich v. Bush*, 2002). The court dismissed the case, holding that individual members of Congress lacked standing to bring the case,

and that the termination question was a political one, and thus nonjusticiable. The judge found the political question reasoning particularly apt because of the nature of the treaty at hand — national defense, representing a potentially key difference with WHO withdrawal. Also, the members of Congress had waited until two days before the withdrawal from the ABM Treaty took effect; Russia may have acted based on this intent in the meantime.

There has been one other key legal development. In the 2012 case *Zivotofsky v. Clinton*, the Supreme Court significantly narrowed the political question doctrine with a two-part test: “[1] where there is ‘a textually demonstrable constitutional commitment of the issue to a coordinate political department; or [2] a lack of judicially discoverable and manageable standards for resolving it.’” (*Zivotofsky v. Clinton*, 2012). Neither condition would be met in the case of WHO withdrawal. The U.S. Constitution does not clearly commit withdrawing from treaties to any branch of government; it is silent on the matter. And there is no special discovery required — this is a straightforward question of constitutional interpretation — or obstacles to the Court's established standards. Accordingly, with the political question not applying, courts should be receptive to a congressional challenge of the president's action.


From all of this, we can also conclude that as a legal matter, the Court has never supported the unilateral prerogative of the president to withdraw from treaties as a general matter. The constitutional authority may be very different for a treaty that touches on a well-recognized presidential power — like recognizing foreign governments — than a multilateral global health treaty. Perhaps most significantly, the conditions that Congress placed on the WHO withdrawal process — implicating its own core power of the purse — point to the unconstitutionality, in this case, of a unilateral presidential withdrawal.

The two conditions that Congress included have two other major implications. First and most significantly, the one-year notice period means that Joe Biden may well be president before the withdrawal could take effect. If Congress and the courts have not already blocked President Trump's move, Biden could, and undoubtedly would withdraw the notice of withdrawal.

And second, even apart from his lack of authority to act unilaterally, the president could not simultaneously withdraw the United States from WHO while withholding any further funding. The United States pays WHO an annual mandatory contribution of about \$120 million per year. Congress has appropriated the money fiscal year 2020, and about half has already been paid. The full amount must be paid as a condition of withdrawal. So must the 15% of the U.S. mandatory balance for fiscal year 2019 still outstanding, and any further money the U.S. government owes WHO, which may be more still. Indeed, the joint resolution refers to the organization's fiscal year, and WHO fiscal years are calendar years, not the U.S. cycle of October to September. The United States would, therefore, have a further balance for 2020, as well as all of 2021, the year that withdrawal would take effect.

Further, when Congress appropriates funds for a given purpose, the president does not have the power to use those funds for another purpose, or forgo using the funds at all. Such actions are

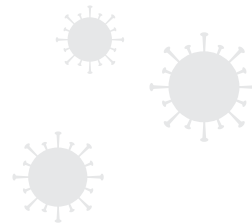
specifically prohibited under the Impoundment Control Act of 1974, and would require express congressional approval.

WHO needs to be strengthened to improve global health security and carry out its broad mandate to advance the right of everyone to the highest attainable standard of health. Congress should not let this administration's decision, undermining both global health and its own authority, go unchallenged. 

Recommendations for Action

Federal recommendations:

- Congress should immediately hold hearings on the legal authority and potential impacts of the president's decision to withdraw from WHO.
- Congress should pass a joint resolution that 1) formally disapproves of President Trump withdrawing from WHO, establishing the clear conflict with the executive that would provide the grounding for a legal challenge, 2) requires continued participation in WHO, and 3) affirms its interpretation of the 1948 joint resolution: that WHO withdrawal would require joint executive and congressional action.
- If the president vetoes the resolution, Congress could override the veto. Alternatively, Congress could pass a concurrent resolution, which does not require presidential signature, though lacks force of law. Either action would bolster Congress's position that a unilateral withdraw violates separation of powers principles.
- Congress should continue funding WHO.
- In appropriating mandatory contributions for 2020 and 2021, Congress should clarify that the funds are being appropriated with intent for the U.S. to remain in the WHO, and not to meet a precondition of withdrawal. This would preclude the possibility of the Trump administration asserting that Congress acquiesced to WHO withdrawal by failing to wield its funding power to block withdrawal by preventing the funding precondition from being met.
- Congress should appropriate voluntary contributions to WHO. As long as Congress does not provide the administration flexibility in how the funds are to be used, the president would have no legal choice under the Impoundment Act but to proceed with providing WHO these funds.
- Congress should pass a resolution to authorize litigation against the president to block withdrawal.



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References

- Bradley C., Swaine E., and Cleveland S. (2017). Authority to Suspend, Terminate, or Withdraw from Treaties. *The ALI Adviser*. Retrieved July 16, 2020, from <http://www.thealiadviser.org/us-foreign-relations-law/authority-suspend-terminate-withdraw-treaties/>
- Constitution of the World Health Organization (WHO), 62 Stat. 2679, 14 U.N.T.S. 186 (1948).
- Goldwater v. Carter, 444 U.S. 996 (1979).
- Hurd H. & Chachko E. (2018). U.S. Withdrawal From the INF Treaty: The Facts and the Law. *Lawfare*. Retrieved July 16, 2020, from <https://www.lawfareblog.com/us-withdrawal-inf-treaty-facts-and-law>
- Koh H. H. (2018). Presidential Power to Terminate International Agreements. *The Yale Law Journal Forum* 128, 432-481.
- Kucinich v. Bush, 236 F. Supp. 2d 1 (D.D.C. 2002).
- Pompeo M. R. (2019). U.S. Withdrawal from the INF Treaty on August 2, 2019 [Press release]. Retrieved July 17, 2020, from <https://www.state.gov/u-s-withdrawal-from-the-inf-treaty-on-august-2-2019/>
- U.S. Department of Defense (2020). DOD Statement on Open Skies Treaty Withdrawal [Press release]. Retrieved July 17, 2020, from <https://www.defense.gov/Newsroom/Releases/Release/Article/2195239/dod-statement-on-open-skies-treaty-withdrawal/>
- United States Participation in Open Skies Treaty, S. 1790 116th Cong. §1234 (2019).
- World Health Organization (WHO) (2020). The WHO Budget Portal. Retrieved June 19, 2020, from <http://open.who.int/2020-21/home>.
- Youngstown Sheet & Tube Co. v. Sawyer, 343 U.S. 579 (1952).
- Zivotofsky ex rel. Zivotofsky v. Clinton, 566 U.S. 189 (2012).



PART 3

**Financing and Delivering
Health Care**

Summary of Recommendations for Financing and Delivering Health Care

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Financing and Delivering Health Care* address private and public insurance, as well as matters of patient and provider safety and care for mental health and substance use disorder. Recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal, state and local guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic.

Action at the Federal Level

- To maximize impact of private insurance plans
 - o Congress should pass legislation waiving cost-sharing obligations and prohibiting balance-billing for out-of-network charges to self-insured plans
 - o HHS should clarify that federal coverage mandates and fee waivers are retroactive to the beginning of 2020 and will continue for the duration of the public health emergency
 - o Congress should extend fee waivers for COVID-19 screening and provide that screening may be conducted by an out-of-network provider as long as the member makes a good faith effort to see an in-network provider
 - o Congress should authorize COBRA subsidies to help workers and their families maintain continuous, comprehensive coverage
 - o Congress should establish a federal vaccination fund, which would allow the federal government, rather than insurance companies or Medicaid programs, to negotiate prices with vaccine manufacturers in order to equitably distribute free virus and serological testing to all Americans as well as reimburse providers for administering these tests based on Medicare rates (Weeks, Private Insurance)
- To maximize the impact of Medicaid, Congress should
 - o Increase the enhanced FMAP by several percentage points and extend it for the duration of the COVID-19 related economic downturn; any enhanced FMAP should condition the extra money on states' implementation of maintenance of effort requirements that prevent cutting eligibility and enrollment
 - o Provide a financial incentive of a 100% FMAP for the first three years of Medicaid expansion to encourage remaining states to adopt the ACA's Medicaid expansion
 - o Offer states an enhanced FMAP for administrative costs
 - o for outreach and enrollment efforts to communicate with newly uninsured people who have lost coverage because of COVID-19 (Huberfeld and Watson, Medicaid)
- To provide coverage for the uninsured, the federal government should increase its support for health care safety net providers by better targeting federal emergency provider grants, giving states greater Medicaid flexibility to help safety net providers, and helping uninsured patients gain access to the Provider Uninsured Claims Fund
 - o HHS should increase the targeted Medicaid Fund and lift restrictions against assisting high-Medicaid-reliant providers that qualify for limited help from the General Fund
 - o Rather than attempting to control distribution, HHS should allocate targeted Medicaid Funds directly to states in order to better ensure a more coordinated strategy with additional state reforms
 - o The HRSA Uninsured Claims Fund should be reformed to operate with greater transparency in terms of which providers receive funding and accessible help for patients in need of financial assistance, including help in languages spoken by the community
 - o HHS should lift restrictions that prevent use of the fund by certain safety net providers Specifically, there should be no bar against receipt of funding by Ryan White Care Act (RWCA) clinics that also receive RWCA funding for costs associated with HIV/AIDS treatment
 - o Congress should appropriate additional direct payment funding to providers
 - o Congress should instruct HHS to open the targeted Medicaid Fund to health care providers obligated under federal, state, or local law to provide free and low-cost care to the uninsured, regardless of whether providers also have received help through the General Fund
 - o Congress should direct HHS to administer the uninsured

- claims fund with greater transparency to patients while restricting access to such funding to hospitals that are deemed DSH hospitals and tax-exempt hospitals that can demonstrate that they maintain a published and accessible financial assistance policy as required under the Internal Revenue Code
- o Congress should give state Medicaid programs the flexibility to make retainer payments to Medicaid providers that furnish elevated levels of health care to medically underserved populations and communities (Rosenbaum and Handley, Caring for the Uninsured)
- To protect patients, staff and visitors in nursing homes,
 - o Congress should
 - Significantly expand OSHA's enforcement resources for effective follow-up on complaints from nursing home and long-term care staff
 - Not pass a federal law granting nursing homes immunity from liability during COVID-19
 - Include the proposed Quality Care for Nursing Home Residents and Workers During COVID-19 Act of 2020 in the next coronavirus relief package or similar legislation that links regulatory oversight with funding to improve quality care and health outcomes
 - o CMS should
 - Mandate adequate staffing ratios in nursing homes and long-term care facilities
 - Withdraw its proposed rule entitled, Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency and Transparency
 - Expand the nursing home dataset to include racial demographics of residents
 - o OSHA should pass legally binding regulations that make employer compliance with PPE and other CDC safety measures compulsory under the General Duty clause
 - o The president should extend the National Guard deployment of assistance to nursing homes and their residents (Skar, Will the Coronavirus Make Us Rethink Quality Care)
- To reap the benefits of telehealth during the COVID-19 pandemic and after
 - o Congress should enact legislation
 - Permitting Medicare and Medicaid reimbursement for patient training and education relating to telehealth digital literacy and encourage providers to target populations with known disparities in telehealth services
 - Permanently extending the telehealth Medicare expansion permitting patients to receive telehealth from new locations, including rural health clinics, Federally Qualified Health Centers and patients' homes
 - Permanently extending Medicare coverage of telehealth services that can be delivered to the same standard of care as comparable in-person services
 - Permanently reducing or eliminating copayments and other out-of-pocket expenses for telehealth services that have demonstrated cost-savings compared to their in-person equivalent service
 - Establishing mechanisms and funding for improving access to telehealth-capable devices for underserved and vulnerable populations
 - o CMS should reduce or eliminate copayments and other out-of-pocket expenses for appropriate telehealth services during the COVID-19 response
 - o HHS and CDC should monitor telehealth policy changes for inequitable outcomes, especially in vulnerable populations (Schmit et al, Telehealth; see also Krueger, Mental Health)
- To assure access to effective care for Substance Use Disorder
 - o Congress should
 - Amend 21 USC § 829(e) to permit clinicians to prescribe buprenorphine for OUD treatment without an initial in-person evaluation, including through audio-only interactions where necessary
 - Amend 21 USC § 823(g)(2) to permit all prescribers registered with the DEA to prescribe buprenorphine for OUD treatment without first obtaining a "waiver"
 - Amend 21 USC § 823(g)(2)(B)(iii) to remove or increase the cap on the number of patients a waived provider may treat with buprenorphine
 - o The Secretary of Health and Human Services (HHS) should
 - In coordination with the Attorney General, use the statutory authority provided by 21 USC § 54(D) to waive the Ryan Haight Act's in-person examination requirement for the duration of the federally-declared opioid emergency
 - Remove restrictions on which patients may receive methadone for OUD by repealing 42 CFR § 812(e)
 - Repeal the requirement in 42 CFR § 812(f)(2) that a prospective OTP patient undergo a "complete, fully documented physical evaluation" before admission
 - Repeal 42 CFR § 812(h)(3)(ii) to remove initial dosing limitations on methadone treatment
 - Modify 42 CFR § 812(i) to liberalize limitations on take-home methadone dosing
 - Modify 42 CFR § 811(a)(1) to permit facilities such as pharmacies that do not meet all the requirements of 42 CFR § 812 to dispense methadone for OUD treatment
 - o The Attorney General should comply with the requirements of 21 USC § 831(h)(2) and promulgate regulations that permit all waived clinicians to prescribe buprenorphine without conducting an in-person examination of the prospective patient
 - o Federal agencies that provide funding to graduate medical education, particularly the Centers for Medicare and Medicaid Services, should condition federal funding of

residency programs on clinicians having received evidence-based instruction in OUD prevention, care, and treatment (Davis and Lieberman, Access)

- To address critical mental health needs, Congress should
 - o Amend the Stafford Act to authorize the Crisis Counseling Assistance and Training Program under public health emergencies when appropriate, and remove the limitation of assistance to nine months following the disaster
 - o Significantly increase funding for providing and marketing for the Crisis Counseling Program in every state
 - o Increase funding for research and culturally competent training in Psychological First Aid
 - o Require regular training in Psychological First Aid as a condition of receipt of emergency preparedness funds, such as Healthcare Preparedness Coalitions
 - o Increase funding for maternal, infant, and early childhood home visiting programs
 - o Increase funding for suicide prevention programs funded through the Garrett Lee Smith Act (Krueger, Mental Health)
- To assure access to abortion services,
 - o The FDA should stop enforcing the outdated Mifepristone REMS protocol so that
 - Physicians no longer have to certify in a written form submitted to the drug sponsor that they have certain required qualifications
 - Mifepristone can be dispensed outside of a hospital, clinic, or medical office, by or under the supervision of a certified healthcare provider
 - o The FDA should issue guidance confirming the results of studies demonstrating medication abortion's safety and efficacy, allowing mifepristone to be ordered through mail-order prescription services and at retail pharmacies
 - o Congress should enact legislation that medical abortion can be a health service appropriately included in plans for telemedicine's expansion
 - o Congress should not exclude funding for teleabortion care in future appropriations COVID-19 relief (Rebouche, Assuring Access)

Action at the State Level

- To maximize the impact of private insurance
 - o States regulators should open Special Enrollment Periods and extend their end-dates for state-operated Marketplaces in all states
 - o Legislatures should enact individual health insurance mandates to stabilize risk pools and provide access to timely and appropriate preventive care and other treatment, rather than allowing individuals to delay and seek care once conditions become acute, as originally intended under the ACA

- o In the event of wholesale repeal of the ACA, legislatures should enact comprehensive reforms, including prohibitions on health-status underwriting and ratemaking
- o Legislatures should enact legislation providing for a "public option," publicly funded health insurance, for those who do not qualify for Medicare, Medicaid, other government health care programs, or ESI, that would be included along with private plans offered on the ACA's state-based marketplaces (Weeks, Private Insurance)
- To maximize the impact of Medicaid, states should
 - o Continue to use the flexible waiver and SPA options offered during the public health emergency to maintain or expand eligibility and streamline application and enrollment processes
 - o Take advantage of the SPA options that allow them to expand eligibility, at least during the public health emergency, to additional uninsured adults and children. These options including raising income eligibility levels and eliminating the five-year waiting period so that immigrant children and pregnant women lawfully residing in the United States can qualify (Huberfeld and Watson, Medicaid)
- States should provide Medicaid and CHIP to all otherwise eligible non-citizens. States should also use their own funds to provide coverage to additional classes of non-citizens (Parmet, Immigration)
- State Medicaid Agencies should adopt the following strategies to help safety net providers
 - o Adjust payment rules rates to recognize extraordinary investment and operational costs incurred in adapting to COVID testing and treatment
 - o Add payment for services furnished in nontraditional care settings and payment for telemedicine care, both of which are permitted under § 1135 of the Social Security Act and through regular state Medicaid plan amendment process
 - o Pursue demonstrations under HHS's Social Security Act § 1115 special research and demonstration authority that enable states to expand eligibility and benefits on an experimental basis
 - o Use Medicaid managed care to expand safety net provider relief, including moving to partial capitation payment methodologies for primary care services furnished by network safety net providers in order to improve revenue flow
 - o Take advantage of an existing federal option to make additional stabilization payments (known as retainer payments) for habilitation and personal care services, even though the administration has barred retainer payments for other types of providers
 - o Instruct their managed care plans to speed the credentialing of out-of-state COVID testing and treatment providers serving residents living in border areas and streamline utilization and medical management requirements (Rosenbaum and Handley, Caring for the Uninsured)

- States should expand and strengthen the duties of tax-exempt hospitals, particularly those with net revenue that exceeds the statewide average
 - o States should supplement tax-exempt hospitals' financial assistance obligations under § 501(c)(3) by setting targeted dollar assistance levels pegged to hospitals' net revenue and should ensure that all tax-exempt hospitals offer accessible application assistance patients, adapted to the languages spoken in the community (Rosenbaum and Handley, Caring for the Uninsured)
- To protect patients, staff and visitors in nursing homes
 - o Nursing home regulators should mandate adequate staffing ratios in nursing homes and long-term care facilities
 - o State administrations should amend or reverse any executive orders that require nursing homes to accept COVID-19 positive patients if they do not have the PPE supplies and ability to adequately isolate them
 - o State governors or legislators should not grant nursing homes immunity from liability during COVID-19
 - o Legislators should significantly expand state OSH agency enforcement resources (Skar, Will the Coronavirus Make Us Rethink Quality Care)
- To reap the benefits of telehealth during the COVID-19 pandemic and after
 - o Legislatures should
 - Lift restrictions on telehealth locations to permit both providers and patients to use telehealth from a safe location, including their homes
 - Limit out-of-pocket expenses by restricting or reducing cost-sharing (eg, co-pays, deductibles) for telehealth services
 - Expand coverage of telehealth services provided by Medicaid and private health plans
 - o Governors and state agencies should use their emergency powers during COVID-19 to
 - Permit new modes of telehealth, including asynchronous, store-and-forward, audio-only (eg, telephone), and secure messaging/email
 - Permit any health care provider to use telehealth for health care services if those services can be delivered to an acceptable level of care
 - Permit out-of-state health professionals that are licensed and in good standing in their home states to practice telehealth within their jurisdiction
 - o Governors and state agencies should vigorously implement telehealth parity laws to support health care providers with falling patient volumes during the COVID-19 response (Schmit et al, Telehealth; see also Krueger, Mental Health)
- To support better access to mental health services
 - o Legislators should
 - Adopt and enforce mental health parity requirements that are at least as strong as federal requirement
 - Increase funding for maternal infant and early childhood home visiting programs
 - Fund mental health education and services in public universities and community colleges
 - Expand funding for trauma informed care and suicide prevention, including targeted efforts to support African-American, Native American, and LGBTQ youth, and other groups at heightened risk
 - o Governors and appropriate state agencies should
 - Consider joining the Psychology Interjurisdictional Compact
 - Require and facilitate education about mental health in K-12 schools, including providing Mental Health First Aid training for teachers and addressing mental health as an aspect of health in K-12 health education courses
 - Require and facilitate education and practice in social and emotional learning skills for all adults involved in school settings, including online learning, and integrate social and emotional learning and skills practice in preschool-12 instruction
 - Incorporate information and skills related to mental health assessment and suicide prevention in continuing education requirements for health care providers (Krueger, Mental Health)
- To assure access to effective care for Substance Use Disorder
 - o Legislators and regulatory agencies should
 - Remove restrictions on OTP siting and forbid localities from imposing such restrictions
 - Authorize the provision of buprenorphine via telehealth where applicable
 - Remove prior authorization and other payment barriers to OAT
 - Require state and local correctional facilities to screen for OUD and offer OAT as appropriate
 - Require all newly licensed physicians to obtain a waiver to prescribe buprenorphine for OAT
 - o Legislators should reform criminal and child protection laws that serve as barriers to treatment access
 - o Regulatory agencies should enable individuals with OAT to access a waived prescriber by calling a single, toll-free number (Davis and Lieberman, Access)
- To assure access to abortion services
 - o Legislators should
 - Repeal cumbersome abortion regulations, such as waiting periods and ultrasound requirements, so that patients can avoid unnecessary visits to clinics and decrease the risk of COVID-19 exposure

- Repeal penalties for self-managed abortion including criminal penalties for extralegal abortion
 - Repeal restrictions on telemedicine as applied to abortion, such as in-person and physician-only administration of medication abortion
 - Include medication abortion among the healthcare services subject to state efforts to expand telemedicine or to relax restrictions on telemedicine
- o Governors and authorized officers should remove restrictions on telehealth modes (include telephone, audio-only communications), locations (permit use at home), delivery (allow any health care provider operating across jurisdictions) from state emergency orders (Rebouche, Assuring Access)
- Governors and other authorized officers should clarify in emergency orders that LGBT-focused services—including access to HIV medication and gender confirmation services—remain essential (Konnoth, Supporting LGBT Communities)

Action at the Local Level

- To remove barriers to effective care for Substance Use Disorder, local governments should modify zoning and licensing laws that create barriers to the establishment of and access to methadone treatment facilities (Davis and Lieberman, Access)

Private Insurance Limits and Responses

Elizabeth Weeks, JD, University of Georgia School of Law

SUMMARY. The COVID-19 pandemic exposed a number of existing flaws in the United States' patchwork approach to paying for and providing access to medical care. Shelter-in-place orders, social distancing, and other public health strategies employed to address the pandemic spawned a global recession, causing rapid and high unemployment rates in many countries. The U.S. unemployment rate peaked in April 2020 at 14.7%, higher than in any previous period since World War II. The United States has long hewed an anachronistic policy of relying heavily on private employers to provide health insurance to a substantial portion of the population. Those who are not eligible for employer-sponsored insurance (ESI) must fend for themselves in the non-group market, unless they qualify for government-sponsored insurance or safety net programs. Companion Chapters in this volume describe the COVID-related challenges for Medicaid and the uninsured, while this Chapter focuses on the private insurance market. The Patient Protection and Affordable Care Act of 2010 (ACA) dramatically overhauled health insurance in the United States. But those reforms have been under continuous threat of dilution or wholesale repeal, including a case currently pending before the U.S. Supreme Court that could strike down the entire Act. Thus, any evaluation of the benefits or demerits of the private insurance market must be read against the possibility that existing consumer protections could be eliminated with the stroke of a pen.

Introduction

The ACA enacted a comprehensive strategy to extend health insurance to more than 20 million previously uninsured individuals and families in the United States. Even at the time of enactment, many viewed the ACA as a fragile compromise and second-best solution to U.S. health care fragmentation. The COVID-19 pandemic casts in stark relief the limits of the ACA's initial design as well as its steady erosion through legal challenges, implementation hurdles, executive orders, and partisan politics. The United States' overreliance on ESI, limited public entitlements, and "Wild West" of an individual insurance market fail to serve the population's health care needs under normal circumstances, not to mention a global pandemic and economic recession.

One component of the ACA's patchwork coverage strategy was expansion of public insurance, namely, Medicaid, to U.S. citizens and qualified non-citizens below 138% of the federal poverty level. But the U.S. Supreme Court later ruled that provision merely optional for states, resulting in 38 states (including Washington, D.C.) expanding Medicaid and 13 not expanding. Another strategy involved significant changes to the market for private health insurance, both ESI, the source of coverage for almost half of the country, and the individual and small-group insurance market, which historically has been fraught with limits, exclusions, and price distortions. The COVID-19 pandemic exposed key coverage

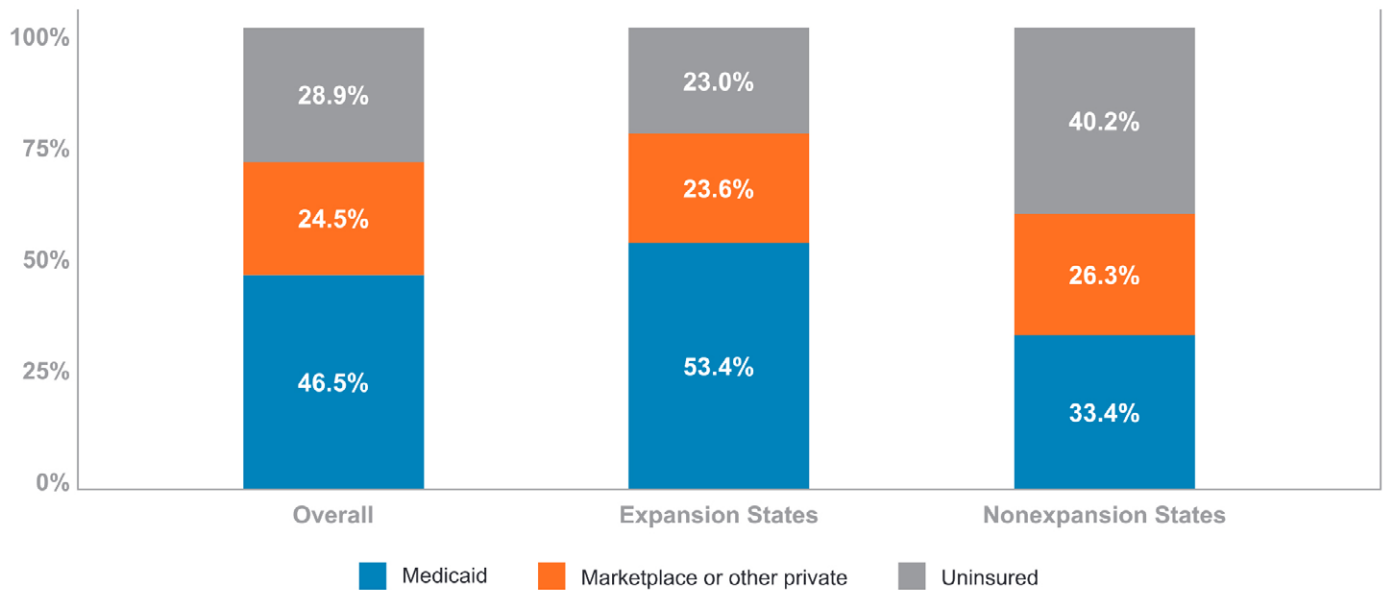
gaps as well as long-standing inequities in health insurance and access to care. Those realities of the existing private insurance market presented numerous difficulties and considerable uncertainty for customers, including coverage for COVID testing and treatment, enrollment restrictions, and unexpected billing for out-of-pocket and out-of-network costs.

ACA Private Insurance Reforms

With respect to ESI, the ACA requires large employers (at least 50 full-time-equivalent employees) to offer affordable, minimum-value coverage to employees. Coverage is "affordable" if self-only coverage costs no more than roughly 10% of the employee's household income. Coverage is "minimum-value" if the plan pays, on average, at least 60% of the cost of covered services. If an employer fails to offer such coverage to a requisite portion of its eligible workforce, it may be subject to an ACA tax penalty called a "shared responsibility" penalty. The shared responsibility penalty is triggered when an employee receives federally subsidized coverage through the ACA's Health Insurance Marketplaces. Small employers are not subject to the shared responsibility penalty but may be eligible for tax subsidies or other assistance to extend coverage to their employees.

With respect to individual and small-group plans, the ACA dramatically overhauled both markets. Two of the key reforms include eliminating pre-existing condition exclusions and

Figure 12.1. Estimated Coverage Types of People Losing Employee-Sponsored Health Insurance



Sources: Urban Institute analysis based on 2017 and 2018 American Community Survey data and 2019 and 2020 monthly Current Population Survey data.
Notes: Medicaid coverage is inclusive of CHIP coverage for children. Coverage changes modeled for US population under age 65.

disallowing premium-rate variation based on individual risk factors, with limited exceptions. Premium-rate variation means insurers may charge different premium rates based on geography (where the plan is sold), plan type (individual or family), age (with a premium variance no greater than 3 to 1), and tobacco use (with a premium variance no greater than 1.5 to 1). Those provisions are significant for COVID-19 coverage because they would seem to allow individuals and families to obtain coverage, without price gouging, even after being diagnosed or for the purpose of being tested.

The Health Insurance Marketplaces are another critical component of the ACA's statutory design to create a more accessible market for private health insurance. Marketplaces operate in each state and facilitate comparison among policies, enrollment, and access to federal subsidies. They may be operated by the state or the federal government. Marketplace plan enrollment is limited to certain times of the year, absent an applicable exception, as described more fully below. Consumers purchasing Marketplace plans are eligible, depending on income level, for two different types of federal subsidies. First, premium-assistance tax credits, which lower monthly premiums, and second, cost-sharing reduction (CSR) payments, which lower out-of-pocket costs for deductibles, co-insurance, and co-payments.

Moreover, all non-group plans, both Marketplace and non-Marketplace, must comply with the ACA's broad coverage mandate, meaning that plans must offer a package of "essential health benefits" (EHB), defined by reference to state benchmark plans, which typically include acute inpatient care, urgent care, emergency room care, and outpatient care. The EHB requirement does not apply to ESI, but ESI plans are assumed to provide similar coverage, if not more. Indeed, the statute defines an EHB package by reference to benefits provided by a typical ESI plan.

Both Marketplace and ESI plans operate under annual Open Enrollment Periods, meaning they are available for enrollment only once a year, for a limited time period. Open Enrollment is subject to certain "life event" exceptions, such as losing health coverage, moving across state lines, getting married or divorced, having or adopting a child, becoming unemployed, or experiencing a death in the family. Those life events trigger Special Enrollment Periods (SEPs), which typically provide 60 days before or after the event to enroll. If the consumer misses the SEP window, she will have to wait until the next annual Open Enrollment Period to apply. These rules limit influx during the plan year, thereby helping insurers better predict costs and set premium rates. They have the effect, however, of preventing, or at least delaying, some consumers from accessing health insurance, even though they cannot be excluded based on preexisting conditions. In the COVID-19 context, that means that individuals without a qualifying life event, seeking insurance outside of the annual Open Enrollment period, would be out of luck.

Coverage Requirements and Out-of-Pocket Limits

Several ACA requirements apply to both ESI as well as individual and small-group plans. For one, plans must cover preventive care, such as screening, vaccinations, and well-child visits, without requiring co-payments, co-insurance, or deductibles, called "first-dollar" coverage. Also, plans may not impose lifetime or annual caps on EHB and are subject to annual out-of-pocket cost limits on covered EHB, meaning all benefits after the limit is hit must be provided without cost-sharing. For 2020, the out-of-pocket limit is \$8,150 for individual coverage and \$16,300 for family policies. Although ESI plans are not required to cover EHB specifically, the EHB definition is relevant for applying these caps.

States may impose additional coverage or other requirements on individual and small-group plans. Those additional requirements, however, do not apply to self-insured ESI plans because of sweeping federal preemption provisions in the Employee Retirement Income Security Act of 1974 (ERISA). About 60% of people who receive insurance through employers are in self-insured plans, meaning that most ESI-insured individuals are in plans not subject to state regulation. That means that even if states enact broader COVID-19 coverage provisions or other consumer protections, a considerable number of insured individuals would not benefit from those reforms. An employer “self-insures” when it bears the financial risk of the medical claims rather than purchasing a group health plan for its employees. Many large employers opt for self-insuring, as it is less costly to directly pay for employees’ medical bills than to pay costly group premiums and underwrite state-mandated benefits. By contrast, under an “insured” ESI plan arrangement, the health insurer is the financial risk-bearer, and the employer pays premiums to the insurer on behalf of the entire group.

Off-Marketplace and Non-ACA-Compliant Plans

In addition to ESI and Marketplace plans, individual and small-group “off-Marketplace” plans are available. Off-Marketplace plans may be similarly comprehensive to other ESI but not eligible for federal premium-assistance or CSR subsidies. Effective with the 2019 plan year, the tax penalty attached to the ACA’s individual health insurance mandate was zeroed out. That means there is no longer any penalty or sanction for failure to carry “minimum essential coverage” in the form of a comprehensive health plan. Accordingly, many people may choose not to purchase insurance at all or may opt for more loosely regulated, less comprehensive plans lacking the ACA’s signature consumer protections and coverage terms. For example, “catastrophic” plans typically have especially high deductibles and cost-sharing obligations without the ACA’s annual out-of-pocket limits, and short-term limited duration (STLD) plans may exclude coverage for pre-existing conditions and EHB,

yet impose annual and lifetime limits. In the first quarter of 2019, an estimated 2.1 million individuals enrolled in off-Marketplace plans, and 1.1 individuals enrolled in non-ACA-compliant coverage. Although some states have responded with individual mandates, coverage mandates, or other measures to prevent proliferation of these substandard plans, individuals going into the COVID-19 pandemic with those sorts of plans may find themselves with very limited coverage and very steep out-of-pocket costs before coverage kicks in.

Insurance Coverage for COVID-19

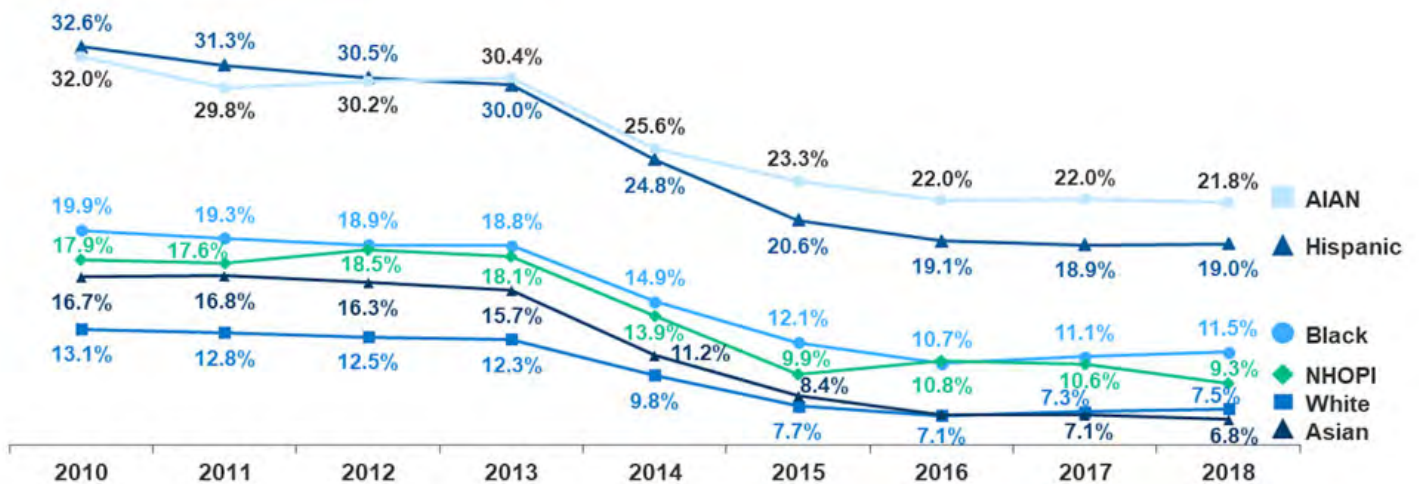
Against that landscape, the COVID-19 pandemic presents a number of challenges for private insurance customers and plans, including coverage for testing and treatment, consumers’ exposure to out-of-pocket or out-of-network costs, and enrollment limitations.

Coverage for Testing

One of the first questions regarding health insurance coverage for the COVID-19 pandemic concerns testing for the virus. The ACA’s “first-dollar” preventive care coverage requirement does not clearly encompass diagnostic testing, yet testing is essential for limiting disease spread by identifying infected individuals who should isolate themselves from healthy individuals. Private health plan cost-sharing requirements might deter individuals from getting tested, thereby undermining those public health strategies.

Congress acted quickly after the United States’ COVID-19 outbreak in spring 2020 to enact two bills containing provisions related to health insurance coverage. The Families First Coronavirus Response Act (FFCRA) and the Coronavirus Aid, Relief, and Economic Security (CARES) Act require all ACA-compliant and other comprehensive group and non-group health insurance plans to cover testing for detection or diagnoses of COVID-19 and the administration of that testing. FFCRA covers testing for both the active coronavirus infection as well as serological tests for the COVID-19 antibody. The coverage requirement only applies

Figure 12.2: Uninsured Rates for the Nonelderly Population by Race and Ethnicity, 2010-2018. Source: Samantha Artiga & Kendal Orgera, Kaiser Family Foundation, 2020



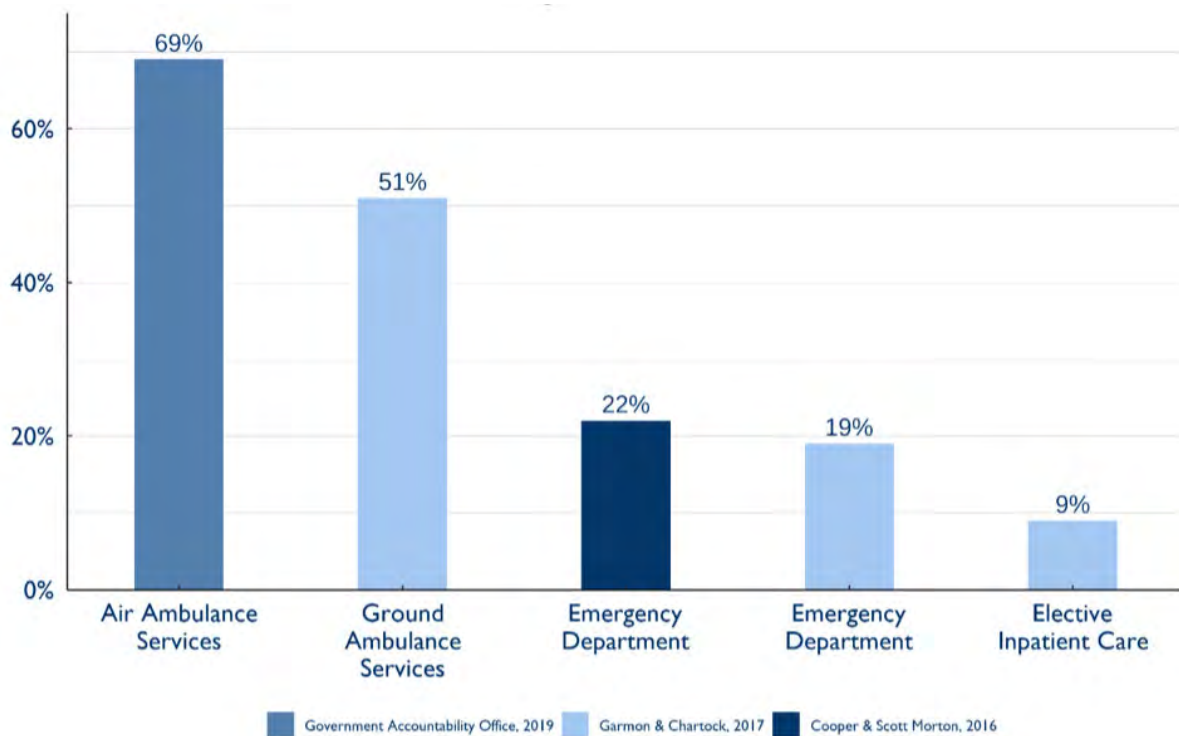


Figure 12.3: Percentage of Visits Leading to Surprise Out-of-Network Bills. Source: Christen Linke Young et al, USC-Brookings-Schaeffer on Health Policy, 2019.

during a federal public health emergency declaration, which HHS Secretary Alex M. Azar II initially declared January 27, 2020 and most recently renewed on April 26, 2020. The HHS Secretary may extend this public health emergency declaration for subsequent 90 day periods, for as long as the COVID-19 public health emergency persists).

Initially, coverage was limited under FFCRA to FDA-approved testing, but the CARES Act extends to (1) tests provided by clinical labs on an emergency basis (including public health labs); (2) state-developed labs; and (3) tests for which the manufacturer says it will seek approval. Coverage also extends to any services or items provided during a medical visit that result in COVID-19 testing or screening. For example, if a patient is screened for influenza to rule out other causes of respiratory illness before the COVID-19 test is administered, the influenza test would be covered (Keith, 2020a).

The laws also specify that COVID-19-related diagnostic testing must be covered like other preventive care under the ACA, that is, without regard to deductibles, co-payments, co-insurance, preapproval, or precertification (Keith, 2020a). Under the CARES Act, plans are required to cover COVID-19 vaccines and other preventive measures on a first-dollar basis, starting 15 business days after the measure is approved. This requirement extends to all types of group health plans, including insured and self-insured ESI plans. The Departments of Labor, Treasury, and Health and Human Services' guidance on FFCRA and CARES Act specifies that testing must be covered when furnished in traditional settings, including physicians' offices, urgent care centers, and emergency rooms, as well as non-traditional settings, such as parking lots, football fields, and other public spaces.

The CARES Act addresses provider reimbursement for COVID-19 diagnostic testing, requiring all comprehensive private health insurance plans to reimburse test providers based on the rate negotiated between the plan and the provider (i.e. the in-network rate). If there is no negotiated rate between the plan and provider (i.e. the provider is out-of-network), then the plan must fully reimburse the provider based on the provider's own, publicly available "cash price" (Keith, 2020a).

Coverage for Treatment

Once an individual is infected with COVID-19 and experiencing acute symptoms, the next concern is coverage for treatment. These questions generally are resolved under the terms of the plan. ACA-compliant plans both on and off the Marketplaces typically include such care under EHB. Likewise, comprehensive ESI plans typically cover treatment services. Since FFCRA and the CARES Act do not address COVID-19-related treatment costs, any applicable coverage limits and cost-sharing requirements would seem to apply (Pollitz, 2020).

Consumers' responsibility for treatment costs vary depending on their plans' cost-sharing configurations, coverage terms, and provider networks. The ACA's annual out-of-pocket limit provides some financial protection, but up until that point, consumers may face some unexpected out-of-pocket costs. While predictable out-of-pocket costs include deductibles and co-payments, unexpected costs could arise from "surprise" medical bills, typically for out-of-network care (Keith, 2020b). For example, if a hospital-employed anesthesiologist or an on-call emergency room doctor treats a patient even though that provider is not covered by the patient's

plan, the provider may later bill the patient directly for the services at out-of-network rates.

Surprise medical billing has been a focus of both state and federal legislative efforts since well before COVID-19. Analysis of emergency room visits covered by large employer plans found that 18% included at least one out-of-network charge. For non-emergency stays at in-network hospitals and facilities, 16% involved at least one out-of-network claim (Pollitz, 2020).

While not addressed in the CARES Act explicitly, federal guidance implementing the Provider Relief Fund portion of the law suggests intent to prohibit surprise billing. One of the terms and conditions attached by the HHS to those relief funds stipulates that for all possible or actual cases of COVID-19, the provider (hospital, clinic, or physician practice) cannot charge more for out-of-pocket care than if the provider were in-network or had contracted with the patient's insurance company (Keith, 2020b).

In addition to the above, rather obscure federal guidance, a handful of state insurance regulators have required or encouraged insurers to waive cost-sharing for COVID-19 testing and treatment (Norris, 2020). In terms of state responses, New Mexico, for example, requires health plans to waive cost-sharing for medical services related to COVID-19, pneumonia, and influenza. Massachusetts requires health plans to provide COVID-19 treatment with no cost-sharing, although the mandate is limited to care in a doctor's office, urgent care clinic, or emergency room, and not the more expensive inpatient care. Vermont requires state-regulated health plans to waive cost-sharing for COVID-19 treatment. Minnesota initially issued guidance suggesting that insurers fully cover the cost of testing and limit or eliminate the cost of treatment, then also called

for further state legislative response. In all cases, state cost-sharing waivers do not apply to self-insured ESI plans due to ERISA preemption, as explained above.

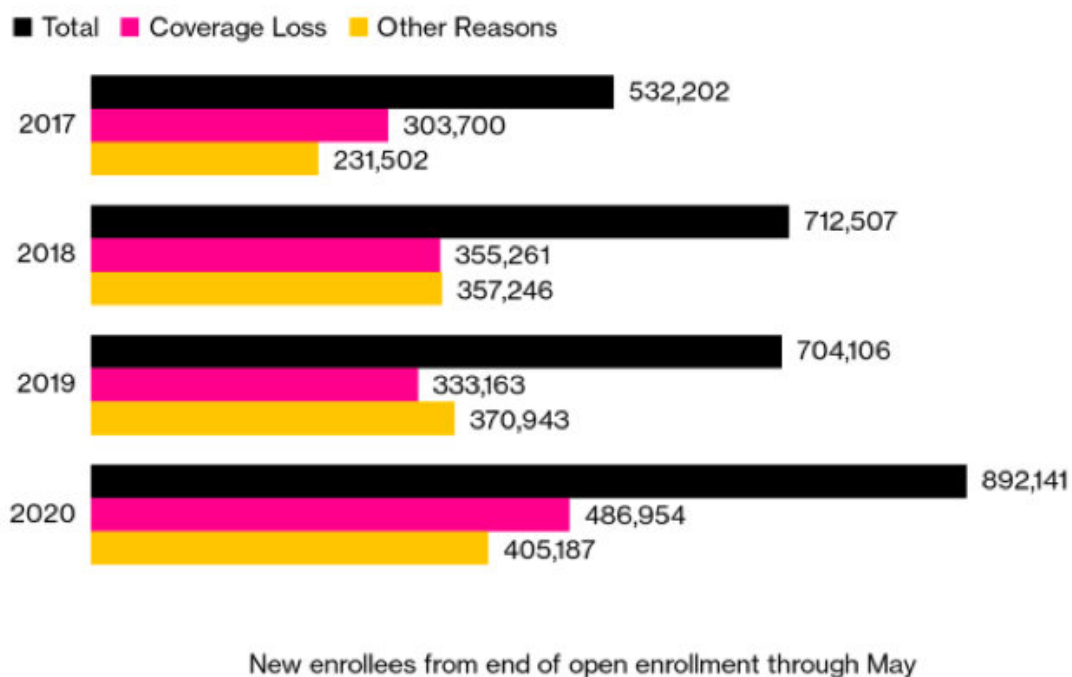
In states where cost-sharing waivers are not required, a few private insurers have voluntarily issued waivers with varying policies. For example, some of these voluntary waivers apply to both in-network and out-of-network treatment, while others waive cost-sharing for any in-network treatment but only out-of-network emergencies. Most commonly, cost-sharing is waived only for in-network treatment, and in some cases, the waivers have date cut-offs or do not extend to self-insured ESI plans (Konrad, 2020).

Open Enrollment Periods

Although the ACA's ban on preexisting condition exclusions would allow individuals who tested positive for COVID-19 to obtain coverage, open enrollment for Marketplace and most ESI plans had already concluded by the time COVID-19 became prevalent in the United States in spring 2020, and the federal government has not opened SEPs in response to the coronavirus pandemic (Norris, 2020). This means that uninsured individuals in states with federally-operated Marketplaces cannot enroll in coverage at this time unless they qualify for a standard SEP. Accordingly, many individuals who had not previously purchased health insurance have found themselves unable to obtain coverage during the pandemic.

U.S. Bureau of Labor Statistics data show that the unemployment rate jumped from 4.4% in March 2020 to a high of 14.7% (20.5 million people) in April 2020, which is around the time that most states issued stay-at-home orders to prevent the virus

Figure 12.4: Marketplace Special Enrollments Spiked Due to COVID-19. Source: Sara Hansard, Bloomberg Law, 2020.



from spreading. Broken down by gender and race/ethnicity, the unemployment rate in April 2020 was 12.8% for white men, 15.8% for white women, 16.4% for Black men, 16.9% for Black women, 16.7% for Latino men, and a whopping 20.2% for Latina women. As a result, the Department of Health and Human Services reported that 487,000 people signed up for Marketplace plans after losing ESI coverage between January and June 2020, which is a 46% increase from the same time period in 2019 (Hansard, 2020b). In April 2020 alone, Marketplace enrollment due to unemployment increased by 139% compared to April 2019.

By contrast, nearly all of the state-run health insurance Marketplaces opened SEPs – irrespective of qualifying life event – in response to the coronavirus pandemic. As of November 1, 2019, 13 states have been operating their own Marketplaces, and all of them except Idaho reopened their Marketplaces to allow uninsured individuals to enroll in ACA-compliant health plans (Norris, 2020). Still, SEP enrollment periods and effective coverage dates vary by state, and all except for Vermont (enroll by August 14, 2020) and the District of Columbia (enroll by September 15, 2020) have already closed.

SEPs triggered by the coronavirus pandemic are designed to let uninsured people gain coverage; they do not allow people with health insurance to switch to different plans. Some non-ACA-compliant health plans, such as STLD, farm-bureau-issued, or health care sharing ministry plans, are not required to cover COVID-19 testing, but enrollees in those plans would be deemed uninsured for purposes of obtaining access to SEPs or possibly Medicaid (Norris, 2020).

Another option for the recently unemployed may be to retain coverage through the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA). COBRA is a long-standing option for former employees to maintain ESI coverage, allowing them to retain access to the same comprehensive plan, provider network, and negotiated group rate for up to 36 months. The downside is that COBRA requires former employees to pay not only their contribution, but also the employers' prior contribution toward the premium, plus a 2% administration fee. In 2019, the average cost of ESI in terms of annual premiums was \$7,188 for single coverage and \$20,576 for family coverage. While the individual was employed, the employer might have paid 80% of that premium for individual coverage and 70% for family coverage (Gangopadhyaya & Garret, 2020). As a result, COBRA coverage is unaffordable for many, especially after losing income from a job.

In prior economic emergencies, Congress authorized subsidies for employees to keep their job-based coverage after being laid off. According to the Treasury Department, COBRA subsidies from the 2009 stimulus package were “especially important for maintaining health insurance coverage for middle-class families during the recession” (Keith, 2020a). While laid-off workers will qualify for SEPs in both state- and federally-operated Marketplaces, potentially with subsidies, COBRA subsidies could help workers and their families maintain continued access to their providers and limit gaps in coverage. 🌟

Recommendations for Action

Federal government:

- HHS should open a Special Enrollment Period for all federally-facilitated Marketplaces as well as self-insured employer-sponsored insurance plans, irrespective of qualifying life events.
- Congress should pass legislation waiving cost-sharing obligations and prohibiting balance-billing for out-of-network charges to self-insured plans.
- HHS should clarify that federal coverage mandates and fee waivers are retroactive to the beginning of 2020 and will continue for the duration of the public health emergency.
- Congress should extend fee waivers for COVID-19 screening and provide that screening may be conducted by an out-of-network provider as long as the member makes a good faith effort to see an in-network provider.
- Congress should authorize COBRA subsidies to help workers and their families maintain continuous, comprehensive coverage.
- Congress should establish a federal vaccination fund, which would allow the federal government, rather than insurance companies or Medicaid programs, to negotiate prices with vaccine manufacturers in order to equitably distribute free virus and serological testing to all Americans as well as reimburse providers for administering these tests based on Medicare rates.

State governments:

- States should open a Special Enrollment Periods and extend their end-dates for state-operated Marketplaces in all states.
- States should enact individual health insurance mandates to stabilize risk pools and provide access to timely and appropriate preventive care and other treatment, rather than allowing individual to delay and seek care once conditions become acute, as originally intended under the ACA.
- In the event of wholesale repeal of the ACA states should enact comprehensive reforms, including prohibitions on health-status underwriting and ratemaking.
- States should enact legislation providing for a “public option,” publicly funded health insurance, for those who do not qualify for Medicare, Medicaid, other government health care programs, or ESI, that would be included along with private plans offered on the ACA’s state-based marketplaces.



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References

- Corlette, S. (2020). I've Been Calling for Greater Private Insurance Coverage of COVID-19 Testing, I've Been Wrong. *Health Affairs Blog*. Retrieved July 9, 2020, from <https://www.healthaffairs.org/doi/10.1377/hblog20200513.267462/full/>
- Gangopadhyaya, A., & Garret, B. (2020). Unemployment, Health Insurance, and the COVID-19 Recession. Retrieved July 9, 2020, from https://www.urban.org/sites/default/files/publication/101946/unemployment-health-insurance-and-the-covid-19-recession_1.pdf
- Hansard, S. (2020a). Telehealth, Tested in COVID-19 Crucible, Expands in Health Plans. Retrieved July 9, 2020, from <https://news.bloomberglaw.com/health-law-and-business/telehealth-tested-in-covid-19-crucible-expands-in-health-plans>
- Hansard, S. (2020b). Obamacare Coverage Spikes After Covid-Related Job Losses. *Bloomberg Law*. Retrieved July 9, 2020, from <https://news.bloomberglaw.com/coronavirus/obamacare-coverage-spikes-after-covid-related-job-losses>
- Jost, T. (2020). Private Health Insurance Coverage in the COVID-19 Public Health Emergency. Retrieved July 9, 2020, from <https://www.commonwealthfund.org/blog/2020/private-health-insurance-coverage-covid-19-public-health-emergency>
- Keith, K. (2020a). COVID-19 Package #3: The Coverage Provisions. *Health Affairs Blog*. Retrieved July 9, 2020, from <https://www.healthaffairs.org/doi/10.1377/hblog20200320.739699/full>
- Keith, K. (2020b). New Guidance to Implement Covid-19 Coverage Requirements and More. *Health Affairs Blog*. Retrieved July 9, 2020, from <https://www.healthaffairs.org/doi/10.1377/hblog20200413.78972/full>
- Kemp, E., St. Louis, M., Lincoln, T., & Tanglis, M. (2020). Insurers' Offers of Free Care for Coronavirus are Often Confusing and Limited. Retrieved July 9, 2020, from <https://www.citizen.org/article/coronavirus-insurance-benefits/>
- Konrad, W. (2020). Does Your Health Insurance Cover You for COVID-19? *CBS News*. Retrieved July 9, 2020, from <https://www.cbsnews.com/news/coronavirus-health-insurance-cover-covid-19-testing-treatment/>
- Norris, L. (2020). COVID-19: State and Federal Efforts to Improve Access to Testing, Treatment, and Health Coverage. Retrieved July 9, 2020, from <https://www.healthinsurance.org/obamacare/state-and-federal-efforts-to-improve-access-to-covid-19-testing-treatment/>
- Pollitz, K. (2020). Private Health Coverage of COVID-19: Key Facts and Issues. Retrieved July 9, 2020, from <https://www.kff.org/coronavirus-covid-19/issue-brief/private-health-coverage-of-covid-19-key-facts-and-issues/>

Medicaid's Vital Role in Addressing Health and Economic Emergencies

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SUMMARY. Medicaid plays an essential role in helping states respond to crises. Medicaid guarantees federal matching funds to states, which helps with unanticipated costs associated with public health emergencies, like COVID-19, and increases in enrollment that inevitably occur during times of economic downturn. Medicaid's joint federal/state structure, called cooperative federalism, gives states significant flexibility within federal rules that allows states to streamline eligibility and expand benefits, which is especially important during emergencies. Federal emergency declarations give the secretary of Health and Human Services temporary authority to exercise regulatory flexibility to ensure that sufficient health care is available to meet the needs of those impacted. Under federal guidance, states have implemented a variety of options to respond to the COVID-19 pandemic. In addition, Congress enacted short-term legislative responses that increase federal funding for Medicaid and open new pathways for eligibility and payment for some COVID-19 testing. These responses have softened the double blow of the pandemic and its attendant recession, but more federal and state action is necessary. Congress should enact an increase in federal funding that lasts beyond the public health emergency to help states ride out the economic impact of the pandemic; provide extra funding to encourage states to adopt Medicaid expansion; offer states more funding for enrollment efforts to reach newly uninsured populations; and require state and local demographic data collection as a condition of federal funding to inform evidence-based public health efforts. State governments should use all available emergency flexibility options to streamline application and enrollment processes and take advantage of increased federal funding possibilities.

Key Features of Medicaid

Medicaid is a 55 year old federal-state program that offers federal funds to states to cover medical care for low-income individuals, including children, parents, people with disabilities, and the elderly. Congress designed Medicaid to address poor patients' needs, prescribing benefits and protections that secure both coverage and care. In 2010, the Patient Protection and Affordable Care Act (ACA) expanded Medicaid coverage to other nonelderly adults, though the Supreme Court made expansion optional in 2012 by deciding that mandatory expansion was unconstitutionally coercive ("National Federation of Independent Business v. Sebelius," 2012). Medicaid expansion has narrowed persistent coverage gaps for low wage workers who are less likely to be offered employer sponsored insurance. Medicaid expansion also narrowed insurance coverage gaps for people of color between 2013-2017, closing the gap between Black and white populations from 11 to 5.3 percentage points, and between Hispanic and non-Hispanic white populations from 25.4 to 16.6 percentage points (Chaudry et al., 2019).

To receive federal matching funds, states agree to abide by federal law, which establishes Medicaid's purpose and structure and requires that states implement mandatory features that sustain Medicaid's role as the nation's safety net. Within that federal structure, states have significant flexibility to make health policy choices that further the purposes of the program. Many state preferences are implemented by exercising optional elements that allow states to do more than baseline federal law requires, such as providing expanded eligibility, additional benefits (including prescription drugs), and use of managed care. Many options can be exercised by submitting a "state plan amendment" (SPA), which describes how a state will implement existing features of federal law and requires only cursory review by the Department of Health and Human Services (HHS). In addition, states may also seek waivers from the secretary of HHS to use Medicaid funds to pay for services not otherwise authorized by federal statute and regulations. Under Section 1115 of the Social Security Act, the secretary of HHS can approve waivers for state applications that seek to further the purposes of the Medicaid program through "demonstration projects" that last for a limited period of time.

Section 1915(c) gives the HHS secretary authority to waive statutory and regulatory requirements to operate home and community based (HCB) long term services and support programs.

Four core features are important for understanding Medicaid's flexible, crucial role in an emergency. First, unlike commercial insurance, Medicaid has unique eligibility rules; these include continuous open enrollment that make coverage available at the moment it is needed; eligibility based on income at the point-in-time of application; retroactive coverage for the three months prior to the date of application (for those who would have been eligible); and the option of presumptive eligibility, which allows access to care during the process of documenting eligibility. Second, Medicaid coverage is comprehensive, providing a wider range of benefits, including long term care, that other payers such as Medicare and commercial insurers do not cover. Third, Medicaid strictly limits beneficiary out-of-pocket payments to ensure that costs are not a barrier to coverage or care, and most patients cannot be refused care or lose coverage if they are unable to pay. Fourth, Medicaid contains due process protections and structural safeguards. For example, beneficiaries are entitled to notice before services are reduced or discontinued. Medicaid is a statutory entitlement for beneficiaries and for states.

States are guaranteed uncapped federal matching funds to help cover the cost of all approved Medicaid services and administration. The Federal Medical Assistance Percentage (FMAP) ranges from 50% to 83% for most services and is based in part on the per capita income of each state, so states with lower incomes relative to the national average have the highest federal match. The FMAP formula reflects states' differing capacity to fund Medicaid, which is usually the second biggest item in a state budget (behind education).

Medicaid spending is also countercyclical. It increases when the economy is weak and more people enroll and decreases when the economy recovers. Federal FMAP support is essential to help states weather recessions and emergencies, because the same events that spark increased enrollment also cause reduced state tax revenue and put pressure on states to cut enrollment, services, or payment to reduce their Medicaid costs. Notably, most state constitutions require balanced budgets, so states rely on the federal government's ability to deficit spend during economic downturns.

States' FMAPs are recalculated annually based on the most recent three years of state per capita income relative to the national average; so, FMAPs for 2020 are based on calendar years 2015–2017. This means that the FMAP formula alone cannot generate immediate relief in a crisis.

Realizing this, Congress has often temporarily increased the federal match by several percentage points (enhanced FMAP or "eFMAP") to help states through economic crises. For example, the Jobs and Growth Tax Relief Reconciliation Act of 2003 increased the FMAP by 2.95 percentage points for five quarters to address the relatively mild downturn of 2001. The American Recovery and Reinvestment Act of 2009 (ARRA) helped states through the

more disruptive Great Recession by providing a minimum eFMAP increase of 6.2 percentage points plus additional state-specific bumps tied to unemployment rates for nine quarters. In 2010, the ARRA eFMAP increase ranged from 6.94 to 13.87 percentage points across states (KFF, 2011). In return for the eFMAP, both laws imposed a "maintenance of effort" requirement so that states could not cut eligibility during the downturns.

Since 2017, one of the most contentious issues for Medicaid has been the Trump administration's novel policy of encouraging states to use Section 1115 demonstration waivers to impose new requirements to make it more difficult for adults eligible under the ACA Medicaid expansion to enroll. HHS has approved waivers allowing 10 states to impose work reporting requirements and other barriers to enrollment including eliminating retroactive eligibility, imposing enforceable premiums, and more frequent eligibility renewal (KFF, 2020). So far, courts have struck down work requirement waivers because HHS failed to consider the decreased coverage they would cause. In Arkansas, the only state to implement such a waiver, 18,000 people (about 25% of those subject to the work requirement) lost coverage in the first five months (*Gresham v. Azar*, 2020).

Despite such attempts to thwart Medicaid expansion and the ACA, over 400 studies show that Medicaid as a whole, and the expansion provided by the ACA in particular, safeguards coverage and access to care for low-income individuals. Medicaid expansion is a crucial tool in improving both individual and public health that addresses social determinants of health and entrenched disparities in health, improving coverage, access, and health for Black and other communities of color, as well as stabilizing state budgets (Guth et al., 2020). Prior to the pandemic, 36 states and the District of Columbia expanded Medicaid eligibility under the ACA. The 14 states that had not expanded before the pandemic began faced an insurance coverage gap exceeding two million people before the pandemic, a number that is steeply increasing as the pandemic progresses and could reach more than 20 million uninsured depending on the pace of the unemployment rate (Garrett & Gangopadhyaya, 2020). These choices are particularly important for communities of color, which are infected and dying at higher rates from COVID-19 (Opiel et al., 2020).

As uninsurance has skyrocketed during the pandemic, nonexpansion states' preexisting health and economic disparities have deepened due to the confluence of the pandemic, the sudden recession it created, and the disparate impact on low-income populations (see Chapter 14 discussing the uninsured). The Congressional Budget Office predicts the national unemployment rate will reach 16% in 2020 and will average at least 10.1% through 2021 (Swagel, 2020). Nonexpansion states' residents tend to depend on sectors that have been hit hard by the recession such as agriculture, retail, and other low-wage jobs, which are less likely to provide employment benefits like health insurance. These same states experience high levels of chronic diseases and other health disparities that inflame the impact of the novel coronavirus.

In short, Medicaid's cooperative federalism structure allows states great flexibility in designing their program, which leads to variable

coverage and benefits across states, which in turn exacerbates disparities in coverage, access to care, and health outcomes. Further, nonexpansion states cannot respond to the novel coronavirus effectively because they are missing a vital tool.

Medicaid's Role in the COVID-19 Pandemic Immediate Response – Medicaid's Flexibility Allowed States to Quickly React

The secretary of HHS declared a COVID-19 public health emergency (PHE) effective January 27, 2020, which triggered special authority for HHS to issue emergency grants, enter into contracts, access emergency funds, and increase regulatory flexibility. Separately, the president declared a national emergency effective March 1, 2020, which made additional federal money available. The two declarations permitted the secretary of HHS to issue emergency-related waivers under Section 1135 of the Social Security Act.

For the duration of the PHE, HHS and states have both their usual and additional Medicaid flexibility to respond to the crisis:

- **Section 1135** of the Social Security Act authorizes the HHS secretary to waive or modify certain Medicaid requirements at a state's request to ensure that sufficient health care services and providers are available during an emergency.
- States with Section 1915(c) waivers for home and community based (HCB) long term care services and supports, which help people to avoid nursing homes and other institutionalization, can quickly get approval to amend those waivers with an **Appendix K** emergency preparedness response request. HHS developed this standalone guidance specifically to help states identify existing Section 1915(c) authority of use during emergencies.

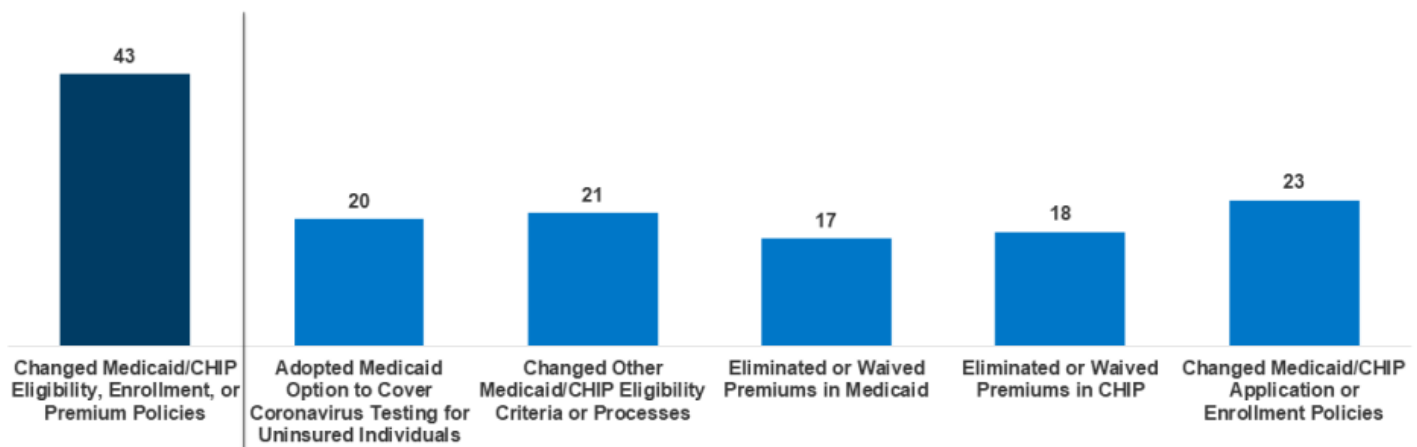
- **Disaster Relief SPAs** allow states to make time-limited changes to their state plans to address access and coverage issues during the COVID-19 emergency.
- States can also use **Section 1115** of the Social Security Act, which authorizes the HHS secretary to waive certain Medicaid provisions to allow states to implement demonstration projects. CMS issued new guidance for states seeking to implement temporary COVID-19 related demonstrations.
- Section 6008 of the **Families First Coronavirus Response Act** (Families First Act) provides congressional authorization for an enhanced FMAP during the PHE, contingent on states maintaining eligibility and enrollment in Medicaid. The Act also gives states the option to cover COVID-19 testing and testing related services for uninsured people with a 100% FMAP.

To facilitate use of these waivers and options, CMS updated its web-based Disaster Response Toolkit, originally prepared to respond to hurricanes and other natural disasters. CMS also created templates for states to use these legal authorities targeted to COVID-19.

All 50 states and the District of Columbia have used some combination of these flexibilities to respond to the COVID-19 emergency. In most cases, states have maintained or expanded eligibility, adapted administration of the program to maximize availability of acute and ICU beds and key equipment like ventilators, and physically separated COVID-19 patients from others. States have also instituted new policies to facilitate access to providers and to assure, and sometimes enhance, provider payment.

Figure 13.1. State Eligibility and Enrollment Policy Changes to Facilitate Access to Medicaid/CHIP Coverage in Response to COVID-19, as of May 21, 2020.

Number of States Making Changes to Eligibility and Enrollment Policies Beyond those Required to Access Enhanced Federal Funding:



NOTES: This table only includes SPA approvals issued to and administrative actions taken by states (including DC) for Medicaid and CHIP. Where states have taken more than one action within a category under multiple authorities, action is counted as taken under SPA authority. States may be pursuing other actions to address COVID-19 through authorities not included in this analysis. SOURCE: KFF analysis of approved SPAs and the Medicaid Disaster Relief SPA Template posted on Medicaid.gov, analysis of state verification plans, as well as analysis of Medicaid actions to address COVID-19 posted on state websites.



The three most common changes states have made are suspending premiums and cost sharing requirements, removing prior authorization requirements, and expanding use of telehealth (Perkins & Somers, 2020). All states have agreed to maintain Medicaid eligibility and enrollment to obtain the Families First enhanced FMAP. Forty-three states have eased eligibility rules even further, including expanding eligibility, eliminating or waiving premiums, and streamlining application and enrollment processes (Dolan & Artiga, 2020).

The COVID-19 emergency Medicaid response also paused the Trump administration's Section 1115 waiver initiatives that create barriers to enrollment for Medicaid expansion adults. To receive the Families First Act enhanced FMAP, states must comply with five maintenance of effort requirements to assure continuous Medicaid coverage. States may not cut Medicaid eligibility or impose more restrictive eligibility procedures; charge higher premiums; disenroll currently or newly enrolled beneficiaries (unless they die, move, or request to be disenrolled); and must cover COVID-19 testing and treatment without cost sharing. These requirements prevent states from instituting new barriers to coverage and from disenrolling anyone for the duration of the PHE.

Section 1135 waivers, disaster relief SPAs, and the Families First Act enhanced FMAP expire when the PHE ends. A PHE declaration remains in effect for 90 days and can be renewed multiple times. The original declaration was renewed April 26, 2020. Unless the PHE is extended again, states will lose many of the Medicaid tools they are using to respond to COVID-19 on July 24.

We cannot yet know whether the emergency options and waivers states have used protected access and continuity of care during

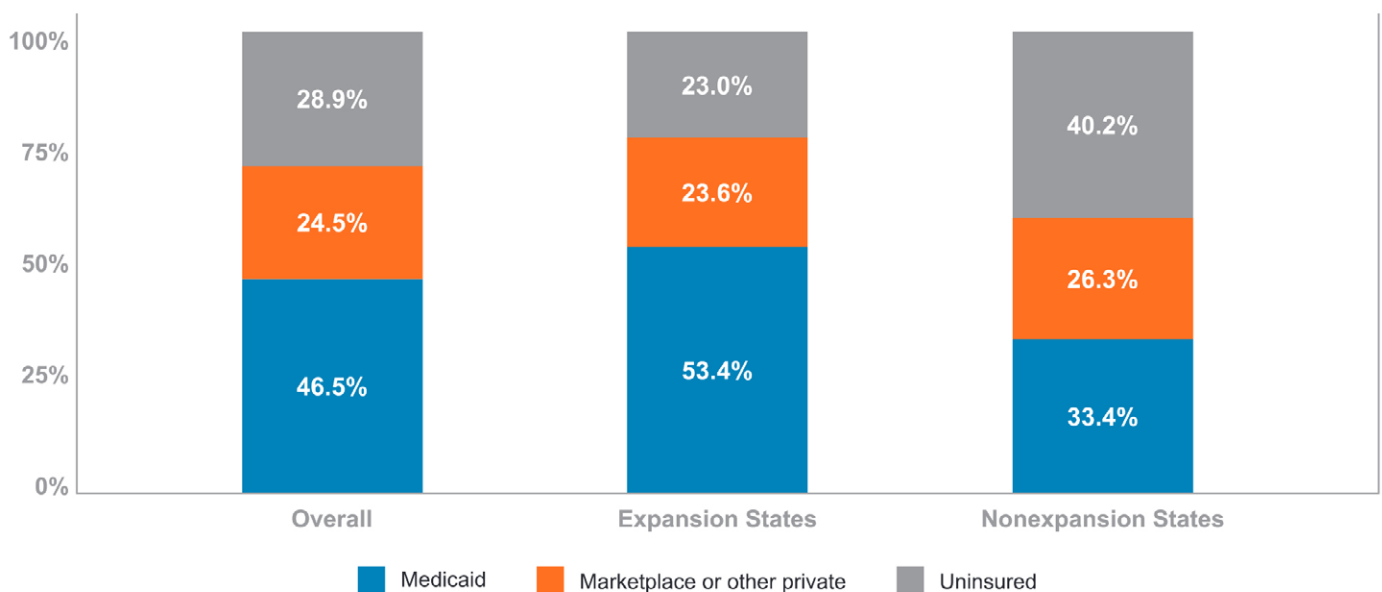
the first wave of the pandemic. Some disaster relief SPAs and 1135 waiver requests were vague, making it difficult to unpack exactly what states are doing. It is also not clear how effectively emergency changes were communicated to enrollees and providers, a particularly salient question during a time when many state workers were working remotely and spotty communication added to the challenges of emergency response. For example, the Trump administration's refusal to open enrollment on the federal health insurance exchange (discussed in Chapter 12) closed a door to enrollment in two-thirds of states and thwarted coherent information about emergency insurance coverage choices for those losing jobs. This choice also impacts Medicaid, because advertising open enrollment encourages engagement with the system through a no-wrong-door application process that can lead to Medicaid enrollment. These issues are particularly acute in a time of emergency.

Looking Forward: COVID-19, Recession, Job Loss, and Enrollment Spikes

The economic fallout of COVID-19 is predicted to be worse than the Great Recession of 2009, with significant implications for Medicaid. The ACA has better positioned state Medicaid and Children's Health Insurance (CHIP) programs to respond to events like COVID-19 by expanding coverage in many states and mandating streamlined and modernized eligibility and enrollment systems for all states. However, eligibility and enrollment policies vary greatly across states, and millions of people will fall through holes in the safety net.

Where a person lives—and whether that state has expanded Medicaid—will dictate coverage or uninsurance. People newly

Figure 13.2. Estimated Coverage Types of People Losing Employee-Sponsored Health Insurance



Sources: Urban Institute analysis based on 2017 and 2018 American Community Survey data and 2019 and 2020 monthly Current Population Survey data. Notes: Medicaid coverage is inclusive of CHIP coverage for children. Coverage changes modeled for US population under age 65.

unemployed during the pandemic will have an easier time qualifying for Medicaid in the states that have expanded Medicaid eligibility. According to a recent study by the Urban Institute, in Medicaid expansion states more than half of people losing employer sponsored insurance are expected to enroll in Medicaid and less than a quarter are expected to become uninsured. In non-expansion states, only about one-third are expected to gain Medicaid coverage while about 40% are expected to become uninsured (Garrett & Gangopadhyaya 2020).

The most significant choice non-expansion states can make to create coverage for people made jobless because of COVID-19 is to adopt the ACA's Medicaid expansion. To encourage states to expand, Congress should provide holdout states with a 100% federal match similar to the one the ACA provided in 2014.

Even in expansion states, almost a quarter of those losing employer coverage because of COVID-19 are predicted to become uninsured. In 2018, nearly a quarter of uninsured adults and children were eligible for Medicaid or CHIP but not enrolled (Artiga et al., 2020). Outreach efforts are needed to let newly uninsured people know about available Medicaid and CHIP options.

Expansion states also should consider other options for increasing Medicaid eligibility. Beyond the ACA Medicaid expansion, states can increase Medicaid income eligibility above 133% of the federal poverty limit (FPL) and receive the Families First Act enhanced FMAP rate. For example, as part of its COVID-19 response, New Mexico expanded eligibility for adults up to 200% FPL (Dolan & Artiga, 2020). Also, states have the option to eliminate the five-year waiting period so that immigrant children and pregnant women lawfully residing in the United States can qualify for Medicaid and CHIP. Another option allows state to provide prenatal care to women regardless of immigration status by extending CHIP coverage through the "unborn child" option (see Chapter 33, Immigration).

To provide adequate financial support for all states, additional federal measures are necessary. The Families First Act offers states an enhanced FMAP during the PHE. However, the Families First Act bump is only about half of the relief that the ARRA provided. The Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act, which passed the House on May 16, 2020, echoes the ARRA's approach and provides a 14 percentage point increase beginning July 1, 2020 through June 30, 2021, but the bill has stalled.

The Families First Act enhanced FMAP, like earlier temporary FMAP enhancements, applies to Medicaid spending that is reimbursed at the state's regular FMAP and indirectly enhances states' CHIP funding. It does not apply to administrative expenses or to Medicaid spending that is already subject to an increased match, including ACA expansion adults (90%), family planning services (90%), services received through Indian Health Services (100%), Medicare cost-sharing assistance for Qualified Individuals (100%), and home health services (90%). This is the first temporary FMAP increase since the ACA Medicaid expansion went into effect, so it is not clear how the failure to include an enhanced FMAP for ACA expansion adults will impact state budgets.

If the PHE declaration is lifted while the economic impact of COVID-19 is still in full force, millions of people will remain out of work and state revenues will continue to be in crisis. Tying the duration of the enhanced FMAP to state jobless rates or other economic conditions, rather than the PHE declaration, would link the eFMAP to the economic drivers of Medicaid enrollment increases. Moreover, using state-specific indicators, like the ARRA did, would amplify the pandemic's geographically disparate impact and states' varying approaches to reopening businesses.

Additionally, Congress should require that states and localities collect consistent demographic data collection as a condition of receiving federal health care funding. This would expand data collection beyond the racial and ethnic data required by section 4302 of the ACA and could be tied to Medicaid or Centers for Disease Control and Prevention (CDC) funding. Better data collection is necessary given wide inconsistencies revealed during the pandemic that complicate responding to the emergency and understanding its impacts. Data regarding race, ethnicity, socioeconomic status, and other key identifying characteristics should not left to the whim of state and local health departments. Reliable evidence is necessary to inform preparation for current and future public health efforts.

Medicaid's federalism structure divides responsibility for low-income populations' medical care between national and state governments and has been both a facilitator and a barrier in the coronavirus response. Medicaid's reliance on state policymaking has allowed some states to use Medicaid's flexibility to respond robustly to the pandemic and others to barely respond, resulting in avoidable risk to health and life. 🌍

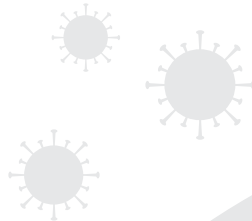
Recommendations for Action

Federal government:

- Congress should increase the enhanced FMAP by several percentage points and extend it for the duration of the COVID-19 related economic downturn; any enhanced FMAP should condition the extra money on states' implementation of maintenance of effort requirements that prevent cutting eligibility and enrollment.
- Congress should provide a financial incentive of a 100% FMAP for the first three years of Medicaid expansion to encourage remaining states to adopt the ACA's Medicaid expansion.
- Congress should offer states an enhanced FMAP for administrative costs for outreach and enrollment efforts to communicate with newly uninsured people who have lost coverage because of COVID-19.
- Congress, HHS, or CDC should require enhanced demographic data collection as a condition of federal health care funding, at all times, so that data regarding key identifying characteristics are collected consistently by state or local health departments.

State governments:

- States should continue to use the flexible waiver and SPA options offered during the PHE to maintain or expand eligibility and streamline application and enrollment processes.
- States should take advantage of the SPA options that allow them to expand eligibility, at least during the PHE, to additional uninsured adults and children. These options include raising income eligibility levels and eliminating the five-year waiting period so that immigrant children and pregnant women lawfully residing in the United States can qualify.



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References

- Artiga S., Rudowitz R., & Musumeci M. (2020). How Can Medicaid Enhance State Capacity to Respond to COVID-19?. Retrieved July 9, 2020 from Kaiser Family Foundation, <https://www.kff.org/coronavirus-covid-19/issue-brief/how-can-medicaid-enhance-state-capacity-to-respond-to-covid-19/>
- Chaudry, A., Jackson, A., & Glied, S. A. (2019). Did the Affordable Care Act Reduce Racial and Ethnic Disparities in Health Insurance Coverage?. Retrieved July 28, 2020 from Commonwealth Fund, <https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/did-aca-reduce-racial-ethnic-disparities-coverage>
- Dolan R., & Artiga, S. (2020). State Actions to Facilitate Access to Medicaid and CHIP Coverage in Response to COVID-19. Retrieved July 9, 2020 from Kaiser Family Foundation, <https://www.kff.org/coronavirus-covid-19/issue-brief/state-actions-to-facilitate-access-to-medicaid-and-chip-coverage-in-response-to-covid-19/>
- Garrett, B., & Gangopadhyaya, A. (2020). How the COVID-19 Recession Could Affect Health Insurance Coverage. Retrieved July 9, 2020 from the Robert Wood Johnson Foundation, <https://www.rwjf.org/en/library/research/2020/05/how-the-covid-19-recession-could-affect-health-insurance-coverage.html>
- Gresham v. Azar, 950 F.3d 93 (D.C. Cir. 2020).
- Guth, M., Garfield, R., & Rudowitz, R. (2020). The Effects of Medicaid Expansion under the ACA: Updated Findings from a Literature Review. Retrieved July 9, 2020 from Kaiser Family Foundation, <http://files.kff.org/attachment/Report-The-Effects-of-Medicaid-Expansion-under-the-ACA-Updated-Findings-from-a-Literature-Review.pdf>
- Kaiser Family Foundation (KFF)(2011). Policy Brief: Impact of the Medicaid Fiscal Relief Provisions in the American Recovery and Reinvestment Act (ARRA). Retrieved July 9, 2020, from <https://www.kff.org/medicaid/issue-brief/impact-of-the-medicaid-fiscal-relief-provisions/>
- Kaiser Family Foundation (KFF)(2020). Medicaid Waiver Tracker: Approved and Pending Section 1115 Waivers by State. Retrieved July 1, 2020, from <https://www.kff.org/medicaid/issue-brief/medicaid-waiver-tracker-approved-and-pending-section-1115-waivers-by-state/>
- National Federation of Independent Business v. Sebelius, 567 U.S. 519 (2012).
- Oppel, R. A., Gebeloff, R., Lai, K. K. R., Wright, W., & Smith, M. (2020). The Fullest Look Yet at the Racial Inequity of Coronavirus. *New York Times*. Retrieved July 9, 2020, from <https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latinos-african-americans-cdc-data.html>
- Perkins, J., & Somers, S. (2020). Medicaid in Transitions-Monitoring COVID-Related Changes in Coverage. Retrieved July 9, 2020 from National Health Law Program, <https://healthlaw.org/resource/medicaid-in-transitions-monitoring-covid-related-changes-in-coverage/>
- Social Security Act § 1135, 42 U.S.C. § 1320b-5 (2019).
- Swagel, P. (2020). CBO's Current Projections of Output, Employment, and Interest Rates and a Preliminary Look at Federal Deficits for 2020 and 2021. Congressional Budget Office. Retrieved July 9, 2020, from <https://www.cbo.gov/publication/56335>

Caring for the Uninsured in a Pandemic Era

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SUMMARY. On the eve of the COVID-19 pandemic, millions of Americans were uninsured despite a booming economy and a decade of health reform. The pandemic and its associated job losses have significantly increased the number of uninsured Americans – predominantly low-income, working-age adults and their families. Underlying drivers are the pandemic-triggered economic crisis, the inherent limits of the Affordable Care Act (ACA), the 2012 United States Supreme Court’s ruling on the constitutionality of its nationwide Medicaid expansion, and policies pursued by the Trump administration and certain states that further restrict the ACA’s reach. Especially serious during a public health emergency, the uninsured are significantly less likely to receive necessary care and are more likely to forgo care because of cost. Health care safety net providers established and operated under federal, state, and local law offer vital care for the uninsured and medically underserved rural and urban populations and communities. Federal COVID-19 legislation enacted to date appropriates funding to directly support health care providers, but the administration’s implementation approach may be limiting the effectiveness of this funding for the highest-need populations and communities. Beyond reforms aimed at improving how federally appropriated emergency health care funding is spent, states should use Medicaid to foster greater safety net provider stability and should pursue policies that promote accountability by tax-exempt hospitals with charity care obligations.

Introduction

Who are the Uninsured and How Has the Pandemic Worsened the Problem?

On the eve of the COVID-19 pandemic – a decade after passage of the Affordable Care Act (ACA), and during a booming economy with historically low unemployment levels – tens of millions of working-age Americans remained uninsured, without access either to employer-sponsored coverage or affordable insurance through Medicaid or the ACA’s health insurance Marketplace. Although the ACA achieved major coverage gains, government data show that in 2018, 8.5% of the population (27.9 million people) were uninsured (Berchick, Barnett and Upton, 2019), an increase of more than one million since 2016 (Tolbert et al., 2019).

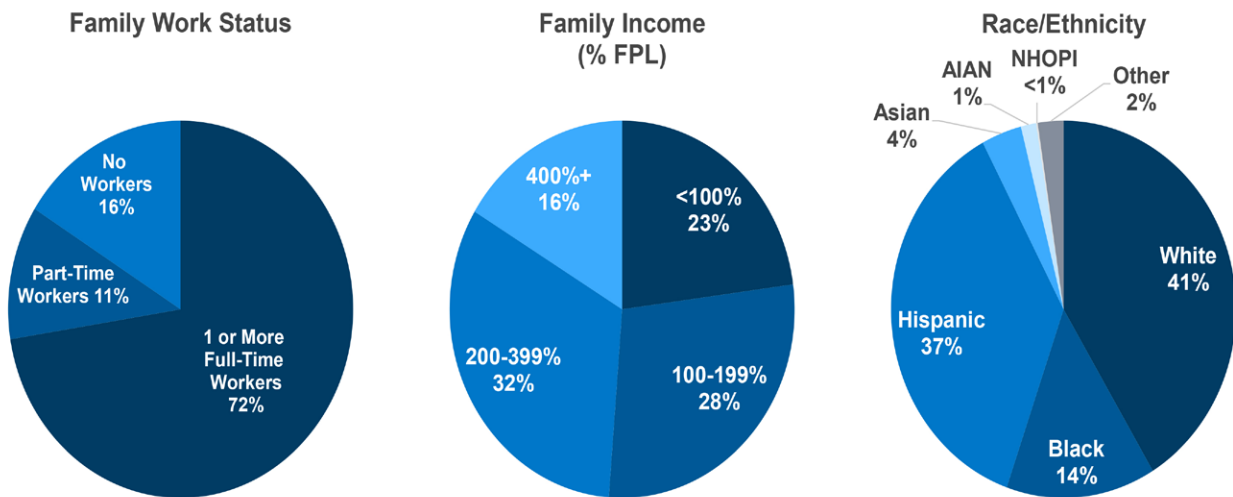
The vast majority of the uninsured (86%) are working-age adults; 83% live in full-time or part-time working households, and 51% have incomes less than twice the poverty level (Figure 14.1). Nearly 60% are racial and ethnic minority Americans, who bear the greatest health risks during the pandemic, and 75% are U.S. citizens. Beyond those uninsured all year, millions more experience intermittent coverage, with frequent interruptions.

States that have not expanded Medicaid tend to have the highest uninsured rates. (Figure 14.2)

The pandemic has illuminated both the ACA’s achievements and limitations. The Medicaid expansion and subsidized Marketplace plans created by the ACA provide a vital coverage lifeline for those without employer plans (See Chapters 12 and 13). But the ACA offers relatively low Marketplace insurance subsidies, leaving policies unaffordable for many (Gunja and Collins, 2019), even as pandemic-induced job loss has heightened the need for an alternative coverage source.

Marketplace shortcomings were exacerbated by the 2012 United States Supreme Court’s decision in *National Federation of Independent Business v. Sebelius*, which effectively transformed the Medicaid expansion into a state option. As of summer 2020, Medicaid expansion remains unimplemented in 14 states. This leaves about 2.3 million poor adults (92% of whom reside in the South) uninsured – too poor to qualify for subsidized Marketplace plans because premium subsidies do not begin until household income reaches 100% of the federal poverty level and yet ineligible for Medicaid (Garfield, Orgera, and Damico, 2020).

The risk of being uninsured is especially pronounced among immigrant populations. As explored at greater length in Chapter 33, the ACA excludes undocumented immigrants from Marketplace subsidies, while publicly-funded coverage is limited to emergency Medicaid. The problem, as Chapter 33 notes, has been further deepened by Trump administration rules that classify Medicaid as a



Total = 27.9 Million Nonelderly Uninsured

NOTE: Includes nonelderly individuals ages 0 to 64. The US Census Bureau's poverty threshold for a family with two adults and one child was \$20,212 in 2018. AIAN refers to American Indian and Alaska Native. NHOPI refers to Native Hawaiians and Other Pacific Islanders. SOURCE: KFF analysis of 2018 American Community Survey, 1-Year Estimates.



Figure 14.1. Characteristics of the Nonelderly Uninsured, 2018

form of public benefit that can threaten people's U.S. legal status.

Decades of research shows that the uninsured are less likely to receive necessary health care and more likely to go without needed care because they cannot afford it (Tolbert et al. 2019). During a pandemic, decisions to avoid care raise the risk of community spread.

Health Care Safety Net Providers and the Response to COVID-19

An Overview of Health Care Safety Net Providers: Mission, Services, and Funding

Safety net providers defined. The health care safety net can be thought of as a class of providers of both institution-based and outpatient care whose principal purpose is to care for low-income and medically vulnerable patients and communities at risk for exclusion because of multiple factors: structural racism; underlying social and economic circumstances; geographic isolation; or disability or health status. Safety net providers are characterized by significantly higher-than-average numbers of Medicaid and uninsured patients and location in, or service to, communities, patients, and populations considered medically underserved because of poverty, elevated health risks, and serious provider shortages.

Beyond what can be thought of as the core health care safety net are tax-exempt hospitals that may not be considered safety net providers but that have a "community benefit" obligation under Section 501(c)(3) of the Internal Revenue Code. At a minimum, this obligation requires tax-exempt hospitals to operate transparent financial assistance programs for patients and to make this

assistance accessible. States and localities may impose additional charity care obligations, such as establishing a minimum level of hospital financial assistance expenditures.

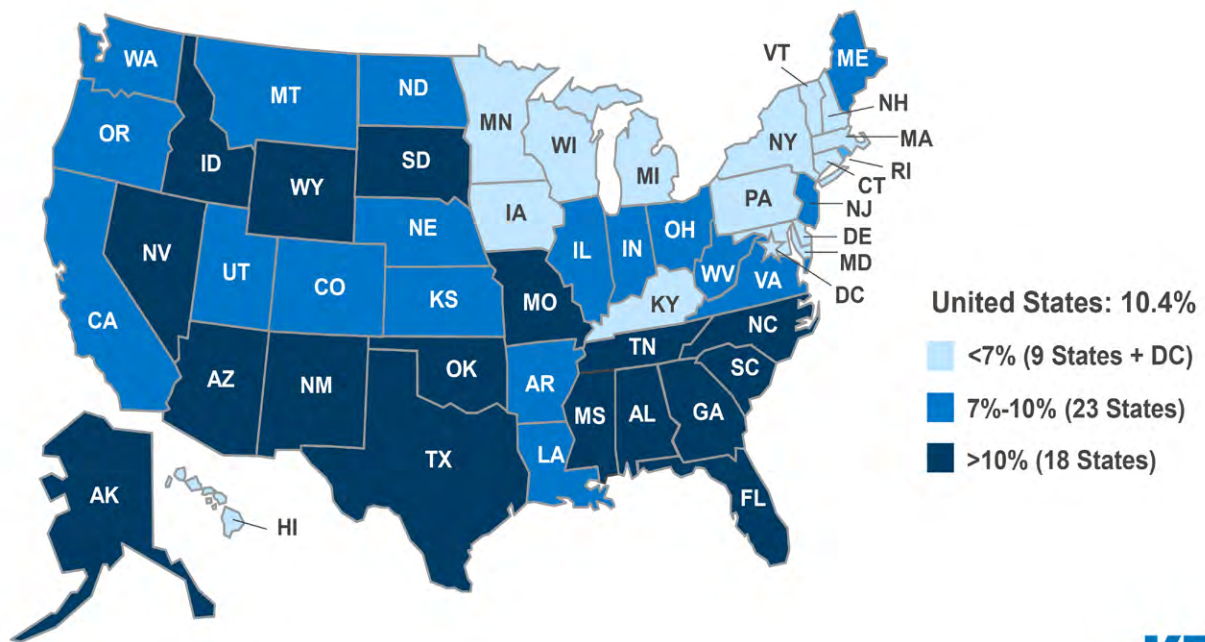
Laws Establishing and Directly Supporting Safety Net Providers

Certain providers assume special prominence in any health care safety net discussion. Some safety net providers operate under the authority of state and local law, such as public hospitals and hospital authorities, state and local health agencies, and community nonprofit health care organizations. Others are creatures of federal law. The Public Health Service Act (PHS Act) establishes community health centers (CHCs), family planning programs, and programs serving people with mental illness and substance use disorders. The Ryan White Care Act funds services for people living with HIV/AIDS. Title V of the Social Security Act authorizes state maternal and child health programs, while the Indian Health Service (IHS) and related programs operate under the Indian Health Care Act.

State laws play a major role in the activities of all safety net service organizations, even in the case of federally-administered programs such as the IHS and CHCs. States regulate health care practice and establish medical liability rules (both the IHS and CHCs are protected against medical liability claims through the Federal Tort Claims Act).

Regardless of the laws under which they operate, safety net providers share certain distinctive features:

- a primary focus on certain vulnerable populations with heightened health and social needs;



NOTE: Includes nonelderly individuals ages 0 to 64.
 SOURCE: KFF analysis of 2018 American Community Survey, 1-Year Estimates.



14.2. Uninsured Rates among the Nonelderly by State, 2018

- services located in or designed to reach low-income and medically underserved communities and populations (e.g., people with serious physical or behavioral health conditions, farmworkers, or people experiencing homelessness);
- provision of free or reduced-cost care to low-income patients;
- services that span health and social service needs and include supportive services such as care management, transportation, translation, and community outreach; and
- financial reliance on a combination of Medicaid and grant or other public support such as dedicated taxes, in the case of public hospital authorities.

The federal grants that fuel safety net provider operations come with conditions of participation, such as location in or service to medically underserved communities, making free and reduced-cost care available to residents of the service area, and making certain types of care available. Examples are CHC and family planning operating grants under the PHS Act, maternal and child health funding under Social Security Act Title V, grants for behavioral health under the PHS Act, and other PHS Act screening and treatment programs administered by state public health agencies and overseen by the Center for Disease Control and Prevention (CDC). States also may provide supplemental grants that create additional requirements regarding services to be offered and populations to be served. Additionally, public hospitals and hospital authorities may receive operating support through dedicated taxes that carry their own service obligations.

Safety net providers are best known for their services targeted to high-need communities, but public hospitals also may be a principal source of highly specialized care for the entire population, such as Level 1 trauma care or highly-advanced newborn intensive care. Furthermore, during a public health pandemic, safety net providers assume a role as public health first responders for their communities, an essential activity for the entire population since pandemics know no geographic boundaries.

The Role of Medicaid Funding

Maintaining a safety net depends virtually entirely on public financing because of the work the health care safety net does and the patients and communities it serves. As the nation’s most important insurer for the low income population, Medicaid is a central funding source for virtually all types of health care safety net providers. Medicaid is essential to health care safety net survival because, as a primary source of insurance for the low income population, it accounts for a major portion source of health care safety net operating revenue. For some safety net providers, Medicaid payment is governed by special rules. For example, payment to CHCs (known as “federally qualified health centers” (FQHCs) under Medicare and Medicaid) is governed by a prospective, per-encounter rate-setting formula known as the prospective payment system (PPS) that applies to both Medicare and Medicaid. This formula effectively yields a bundled, per-encounter rate for covered services tied to operating costs. The PPS system also governs payments to rural health clinics (RHCs) designated as such under Medicare and Medicaid because of their location in rural,

medically underserved communities experiencing primary care shortages and their use of midlevel health professionals, such as nurse practitioners and physician assistants. Hospitals may qualify for disproportionate share hospital (DSH) payments under Medicare and Medicaid and also may be deemed Critical Access Hospitals (CAH) for purposes of payment under both programs.

States also have substantial leeway to shape safety net provider Medicaid payment rules. They have the flexibility to recognize costs not typically paid in private practice settings (e.g., care management, transportation, translation), compensate providers at higher rates given greater intensity of care needs, or pay for services in offsite settings such as homeless shelters or farmworker camps.

By reducing the financial burden of uncompensated care, Medicaid’s (DSH) payment system is especially important for safety net hospitals (MACPAC 2020). Unlike the general Medicaid program, federal DSH payments to states are subject to an aggregate upper limit. Although states have considerable leeway over how to allocate their annual DSH allotments, certain hospitals are “deemed” (i.e., mandatory) DSH recipients because they treat an exceptionally high level of low-income patients. These hospitals may also receive other supplemental Medicaid payments authorized under law.

Medicaid’s centrality to the safety net is evident in its role as a funder of care. The program is the single largest funder of HIV/AIDS care, family planning services for low-income patients, and treatment for people experiencing serious mental illness or substance use disorders. CHCs derive 44% of their operating revenue from Medicaid (Rosenbaum et al., 2019). Compared to other hospitals, safety net hospitals derive a significantly greater proportion of their operating revenue through Medicaid (MACPAC 2016). Medicaid insures one in four IHS patients (IHS, 2020).

As patient visits and admissions for non-COVID reasons have plummeted during the pandemic, so has Medicaid revenue, creating a major survival test for safety net providers, even as their costs of adapting to and treating COVID have skyrocketed. Weekly federal CHC reporting data provide insight. Over the April-June period alone, CHCs experienced a 38% visit decline nationwide, with an estimated \$3.2 billion in Medicaid revenue losses (Shin et al., 2020). Federal CHC funding alone is far below the amount needed to offset steep insurance revenue losses, and safety net providers have reduced services, closed sites, and laid off staff. Telehealth likely has mitigated some of the losses, particularly for primary care, but the jury is out on how well telehealth can substitute for in-person care in the case of medically vulnerable patients and on how effective telehealth has been in keeping providers afloat.

Figure 14.3. COVID-19 Provider Relief Fund: Overview of HHS Distributions to Date¹

General Distribution \$50 Billion	<ul style="list-style-type: none"> • Tranche 1: \$30 billion to Medicare providers based on their share of total 2019 Medicare fee-for-service expenditures <i>Distributed April 10 and April 17</i>
	<ul style="list-style-type: none"> • Tranche 2: \$20 billion to Medicare providers based on the <u>lesser</u> of 2% of a provider’s net patient revenue or the sum of incurred losses for March and April. <u>If a provider’s Tranche 1 payment is at least 2% of annual patient revenue, it may not receive a Tranche 2 payment</u> <i>Distributed on a rolling basis to providers that submitted the required data by June 3</i>
Medicaid Distribution ~\$15 Billion	<ul style="list-style-type: none"> • \$15 billion to providers that: (1) billed Medicaid (managed care or fee-for-service) between January 1, 2018 and December 31, 2019; and (2) have <u>not</u> received a General Distribution payment. Payments will be at least 2% of annual patient revenue <i>HHS launched an enhanced portal for providers to submit applications by July 20; payments made on a rolling basis</i>
Hot Spot Hospitals \$22 Billion	<ul style="list-style-type: none"> • \$12 billion to the 395 hospitals that provided inpatient care to 100+ COVID-19 patients through April 10 <i>Distributed on or around May 1</i>
	<ul style="list-style-type: none"> • \$10 billion based on COVID-19-positive inpatient admissions through June 10 (methodology TBD) <i>Providers were required to submit data via TeleTracking by June 15 at 9:00 pm ET; distribution timing and methodology TBD</i>
Safety Net Hospitals \$10 Billion	<ul style="list-style-type: none"> • \$10 billion to safety net hospitals defined as having: (1) a Medicare Disproportionate Patient Percentage (DPP) of 20.2% or greater (2) average uncompensated care per bed of \$25,000 or more (3) profitability of 3% or less, as reported to CMS in its most recently-filed cost report. Payments will be based on each hospital’s share of “individual facility scores” (number of facility beds multiplied by DPP) among all qualifying hospitals <i>Distributed on or around June 12</i>
Rural Providers \$10 Billion	<ul style="list-style-type: none"> • \$10 billion to rural acute care general hospitals, Critical Access Hospitals, Rural Health Clinics and Community Health Centers located in rural areas <i>Distributed on or around May 1</i>
Uninsured Claims Unspecified	<ul style="list-style-type: none"> • Unspecified amount based on claims submitted to HHS by providers for testing or treating uninsured COVID-19 patients on or after February 4 (reimbursed at Medicare rates) <i>Claims reimbursement is ongoing; payments began on May 18</i>
IHS \$500 Million	<ul style="list-style-type: none"> • \$500 million for Indian Health Service (IHS) facilities <i>Distributed on or around May 22</i>
Dentists Unspecified	<ul style="list-style-type: none"> • HHS is “working on an additional allocation to distribute relief broadly to dentists”

- HHS has distributed/is currently distributing payments
- Payments have not yet been made
- June 9-announced allocations

1. Manatt Health analysis, based on HHS’ June 9 press release; HHS Provider Relief Fund FAQs as of June 20, 2020; and Medicaid/CHIP Provider Relief Fund Payment Forms and Guidance.

The Federal Response To Date

By early June, Congress had enacted four laws that together establish a series of public and private insurance reforms (which are explored in other chapters) as well as direct emergency health care funding aimed at covering the cost of the COVID response and stabilizing health care providers. In addition to the Provider Paycheck Program (PPP), for which health care providers may be eligible, these laws provide \$175 billion in funding to offset provider losses and help defray unreimbursed COVID-related costs.

Figure 3 shows the various funding streams available to health care providers directly. Essentially, the Trump administration has established two online distribution mechanisms: the CARES Act Provider Relief Fund, and a COVID-19 provider uninsured claims reimbursement fund to cover testing and treatment costs (HRSA, 2020). The uninsured claims reimbursement fund operates as a capped \$2 billion federal allocation covering claims in connection with testing or treatment for “uninsured individuals with a COVID-19 diagnosis on or after February 4, 2020.” Because a diagnosis is needed, asymptomatic testing costs appear to be excluded. According to the administration, provider payments “generally” will be at Medicare rates, “subject to available funding.”

The Provider Relief Fund consists of a general fund as well as a series of “targeted” funds aimed at specific providers and populations: rural health; “high-impact distribution”; skilled nursing facilities; Indian Health Service (including IHS urban centers); “safety net” hospitals; and Medicaid providers as well as providers caring for children insured through separately-administered Children’s Health Insurance Programs (CHIP). (Most states now use their CHIP funding at least in part to enhance coverage for children through Medicaid rather than separate CHIP plans).

The Medicaid targeted fund was not unveiled until weeks after the general fund came online, after protests by Congressional leaders, state Medicaid agencies, and Medicaid experts pointed to the length of time taken to move funding into action for the highest-need communities. Experts also pointed to the General Fund’s built-in bias against providers, since to date the Fund has favored providers with high net revenue, while safety net providers typically have very low operating margins. The Medicaid Fund bars aid to Medicaid and CHIP providers that received any amount of assistance from the General Fund, even though they would have had no way of knowing about a Medicaid Fund as yet to be established, and even if they return the General Fund allotment they received. Indeed, administration policy provides that simply being eligible for small payments out of the General Fund is enough to disqualify safety net providers from receiving targeted Medicaid funds. Moreover, unlike the other funds, applicants to the Medicaid Fund must go through additional procedural steps. Further complicating matters, in developing the Medicaid Fund, the Trump Administration devised its own distribution formula rather than consulting closely with state Medicaid agencies regarding the criteria and qualifications that should guide the allocation process.

The shortcomings evident in the Medicaid Fund must be understood against the fact that the administration also has refused to give Medicaid agencies flexibility to provide additional assistance to hard-hit providers in the form of grants that do not have to be repaid – something that past administrations, Republican and Democratic alike, have permitted (Rosenbaum and Handley, 2020). 🌞

Recommendations for Action

Federal government:

- The federal government should increase its support for health care safety net providers by better targeting federal emergency provider grants, giving states greater Medicaid flexibility to help safety net providers, and helping uninsured patients gain access to the Provider Uninsured Claims Fund.
- HHS should increase the targeted Medicaid Fund and lift restrictions against assisting high-Medicaid-reliant providers that qualify for limited help from the General Fund.
- Rather than attempting to control distribution, HHS should allocate targeted Medicaid Funds directly to states in order to better ensure a more coordinated strategy with additional state reforms.
- The HRSA Uninsured Claims Fund should be reformed to operate with greater transparency in terms of which providers receive funding and accessible help for patients in need of financial assistance, including help in languages spoken by the community.
- HHS should lift restrictions that prevent use of the fund by certain safety net providers. Specifically, there should be no bar against receipt of funding by Ryan White Care Act (RWCA) clinics that also receive RWCA funding for costs associated with HIV/AIDS treatment.
- Congress should appropriate additional direct payment funding to providers.
- Congress should instruct HHS to open the targeted Medicaid Fund to health care providers obligated under federal, state, or local law to providing free and low-cost care to the uninsured, regardless of whether providers also have received help through the General Fund.
- Congress should direct HHS to administer the uninsured claims fund with greater transparency to patients while restricting access to such funding

to hospitals that are deemed DSH hospitals and tax-exempt hospitals that can demonstrate that they maintain a published and accessible financial assistance policy as required under the Internal Revenue Code.

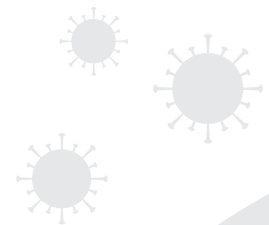
- Congress should give state Medicaid programs the flexibility to make retainer payments to Medicaid providers that furnish elevated levels of health care to medically underserved populations and communities.

State governments:

- State Medicaid Agencies should adopt the following strategies to help safety net providers.
- States should consider adjusting payment rules rates to recognize extraordinary investment and operational costs incurred in adapting to COVID testing and treatment.
- States should add payment for services furnished in nontraditional care settings and payment for telemedicine care, both of which are permitted under § 1135 of the Social Security Act (Rosenbaum, 2020) and through regular state Medicaid plan amendment process.
- States should pursue demonstrations under HHS's Social Security Act § 1115 special research and demonstration authority that enable states to expand eligibility and benefits on an experimental basis.
- States should use Medicaid managed care to expand safety net provider relief, including moving to partial capitation payment methodologies for primary care services furnished by network safety net providers in order to improve revenue flow.
- States should take advantage of an existing federal option to make additional stabilization payments (known as retainer payments) for habilitation and personal care services, even though the administration has

barred retainer payments for other types of providers.

- States also should instruct their managed care plans to speed the credentialing of out-of-state COVID testing and treatment providers serving residents living in border areas and streamline utilization and medical management requirements.
- States should expand and strengthen the duties of tax-exempt hospitals, particularly those with net revenue that exceeds the statewide average.
- States should supplement tax-exempt hospitals' financial assistance obligations under § 501(c)(3) by setting targeted dollar assistance levels pegged to hospitals' net revenue and should ensure that all tax-exempt hospitals offer accessible application assistance patients, adapted to the languages spoken in the community.



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References

- Berchick, E. R., Barnett, J. C., & Upton, R. D. (2019). Health Insurance Coverage in the United States: 2018 Retrieved July 7, 2020, from [https://www.census.gov/library/publications/2019/demo/p60-267.html#:~:text=The%20percentage%20of%20people%20with,in%202017%20\(92.1%20percent\)](https://www.census.gov/library/publications/2019/demo/p60-267.html#:~:text=The%20percentage%20of%20people%20with,in%202017%20(92.1%20percent))
- Garfield, R., Orgera, K., & Damico, A. (2020). The Coverage Gap: Uninsured Poor Adults in States that Do Not Expand Medicaid Retrieved July 7, 2020, from <https://www.kff.org/medicaid/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid/>
- Gunja, M. Z. & Colins, S. R. (2019). Who are the Remaining Uninsured, and Why Do they Lack Coverage? Retrieved July 7, 2020, from <https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/who-are-remaining-uninsured-and-why-do-they-lack-coverage>
- Health Resources & Services Administration ("HRSA") (2020). COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Retrieved July 7, 2020, from <https://www.hrsa.gov/CovidUninsuredClaim#:~:text=President%20Trump%20is%20providing%20support,The%20President%20signed%20the%20bipartisan%3A&text=Within%20the%20Provider%20Relief%20Fund,uninsured%20individuals%20with%20COVID%2019>
- Indian Health Service ("IHS") (2020). IHS Profile Retrieved July 7, 2020, from https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/factsheets/IHSProfile.pdf
- Medicaid and CHIP Payment and Access Commission ("MACPAC") (2020). Issue Brief: Medicaid Base and Supplemental Payments to Hospitals Retrieved July 7, 2020, from <https://www.macpac.gov/wp-content/uploads/2019/03/Medicaid-Base-and-Supplemental-Payments-to-Hospitals.pdf>
- Medicaid and CHIP Payment and Access Commission ("MACPAC") (2016). Report to Congress on Medicaid Disproportionate Share Hospital Payments Retrieved July 7, 2020, from <https://www.macpac.gov/wp-content/uploads/2016/01/Report-to-Congress-on-Medicaid-DSH.pdf>
- Rosenbaum, S., Sharac, J., Shin, P. and Tolbert, J. (2019). Community Health Center Financing: The Role of Medicaid and Section 330 Grant Funding Explained Retrieved July 12 from <https://www.kff.org/report-section/community-health-center-financing-the-role-of-medicare-and-section-330-grant-funding-explained-issue-brief/>
- Rosenbaum, S. & Handley, M. (2020). Broadening Medicare's Accelerated and Advance Payment Program to Save Health Care Providers that Serve Our Most Vulnerable Populations Retrieved July 7, 2020, from <https://www.commonwealthfund.org/blog/2020/broadening-medicare-accelerated-and-advance-payment-program-save-health-care-providers>
- Rosenbaum, S. (2020). Using Medicaid Waivers to Help States Manage the COVID-19 Public Health Crisis Retrieved July 7, 2020, from <https://www.commonwealthfund.org/blog/2020/medicaid-waivers-states-covid-19>
- Shin, P., Sharac, J., Hernandez, J., Velasquez, M., Morris, R., Rosenbaum, S., & Jacobs, F. (2020). Key Updates from the Health Center COVID-19 Survey (Update #8): Nearly 2,000 Sites are Temporarily Closed, Testing Has Dropped, Telehealth Use Has Declined, and Revenue Losses are Estimated in the Billions Retrieved July 7, 2020, from <https://www.rchnfoundation.org/wp-content/uploads/2020/06/Week-8-HRSA-COVID-19-Update-Final-6-2-20-3.pdf>
- Tolbert, J., Orgera, K., Singer, N., & Damico, A. (2019). Issue Brief: Key Facts About the Uninsured Population Retrieved July 7, 2020, from <http://files.kff.org/attachment/Issue-Brief-Key-Facts-about-the-Uninsured-Population>

Assuring Access to Abortion

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SUMMARY. Over the spring of 2020, numerous states announced measures suspending abortions in response to COVID-19. Banning abortion during the pandemic is counterproductive. Impeding access to abortion will not help preserve healthcare resources. Moreover, prohibiting access to abortion care exacerbates the strain on the healthcare system. People who lack access to abortions will travel to neighboring states, induce their own abortions, or carry pregnancies to term, which will require prenatal care and assistance in childbirth. Perhaps more importantly, the people hit hardest by suspending abortion care are those for whom the pandemic already has had devastating effects. Lifting restrictions on medication abortion and expanding telehealth abortion services will conserve healthcare resources and improve public health. Recognizing the advantages of telemedicine, some states, as well as the federal government, have relaxed restrictions on remote diagnosis and treatment. However, many of those same states have carved out exceptions for abortion in their telemedicine policies. In addition, people seeking medication abortions still face unnecessary restrictions on access, none of which are applied to comparable office-based procedures. Policymakers can eliminate barriers to safe abortion services now and in the future. “No-touch” terminations, in which all medical supervision happens over the telephone or online, can better accomplish the goals that the present abortion suspensions cannot. Telehealth for medical abortion can ease the burdens on pregnant people, healthcare workers, and health systems in light of the unprecedented challenges presented by COVID-19.

Introduction

Twelve states suspended abortion care, for differing lengths of time, in response to COVID-19 (Sobel et al., 2020). State officials argued that the policies classifying abortion as a nonessential surgery reduced patient-physician contact as well as preserved medical supplies, hospital space, healthcare capacity. All but two courts were unpersuaded by these arguments and issued injunctions of the orders after holding that the bans violated patients’ constitutional right to an abortion, ignored medical evidence on the short-term and long-term consequences of delayed abortion care, and exacerbated the public health emergency by ultimately increasing pregnant people’s use of healthcare systems.

This Chapter summarizes 12 states’ classification of abortion as non-essential health care during the onset of the pandemic. It then examines the present restrictions on medication abortion that undermine efforts to curb the spread of COVID-19. Given the challenges presented by COVID-19, state and federal policy should permit teleabortion to the extent it is feasible and suspend medically unnecessary requirements, such as in-person consultations and pre-abortion ultrasounds, that increase clinic-patient contact. Enabling remote access to abortion would ease the already-heavy burdens that fall disproportionately on low income and people of color, whose lack of access to abortion has deep and longstanding health effects.

State Abortion Care Suspensions

In March and April of 2020, 12 states issued executive orders and public health directives that either implicitly or explicitly suspended abortion services during the COVID-19 emergency. In all but one state (Arkansas), these policies were enjoined by courts, lifted after settlements with state officials, or expired when executive orders expired.

COVID-19 Orders Blocked through Litigation

Four states implemented executive orders, issued by the governor or the state’s public health department, that limited access to or resulted in a complete ban on abortion services. The following states’ policies were enjoined in litigation in which courts held that suspension of non-essential services did not apply to abortion and the bans contravened women’s constitutional rights to abortion before viability.

In Alabama, the state’s public health officer issued an order on March 27, 2020, which postponed surgical procedures not necessary to treat an “emergency medical condition” or “avoid serious harm from an underlying condition.” Abortion providers won a temporary restraining order on March 30, 2020, in federal district court, which the Court of Appeals for the Eleventh Circuit affirmed. At the end of April 2020, an amended order permitted surgical procedures that included abortion care.

In Ohio, on March 17, 2020, the director of the state health department prohibited all nonessential surgeries and procedures that utilized personal protective equipment (PPE), including abortion services. The state's attorney general sought to enforce the order against abortion providers through cease and desist letters. Providers sued for a preliminary injunction, and the federal district court ruled that physicians may determine, on a case-by-case basis, whether an abortion procedure was "necessary because of the timing vis-à-vis pre-viability; to protect the patient's health or life; and due to medical reasons...." The Court of Appeals for the Sixth Circuit affirmed, holding that the order erected an "undue burden" on the constitutional right to abortion. By May 1, 2020, a new order reinstated all non-essential surgeries and procedures, including abortion.

On March 15, Oklahoma's governor issued an executive order postponing all elective surgeries and minor medical procedures. A state press release interpreted the order to apply to all abortions unless the procedures were necessary to prevent serious health risks or in response a medical emergency. Providers won a temporary restraining order that created exceptions for medication abortion and for patients nearing the gestational legal limit; the Court of Appeals for the Tenth Circuit affirmed. All abortion services resumed on April 24, 2020 when some elective surgeries resumed.

The governor of Tennessee issued an executive order that prohibited procedures, including abortion services, that were not necessary to address a medical emergency or to preserve the health and safety of a patient as determined by a licensed medical provider. Providers filed for a preliminary injunction, which the district court granted on April 17, 2020, on constitutional grounds. The Court of Appeals for the Sixth Circuit affirmed.

Texas' legal path was particularly twisting, and the litigation over the state's abortion suspension illustrates the arguments for and against the banning abortion as a pandemic-prevention measure. The governor issued an executive order on March 22, 2020 mandating all licensed health care professionals and facilities postpone surgeries and procedures not immediately medically necessary. The state's attorney general applied the order to abortion care unless there was a threat to the life of the pregnant person, and the Texas Medical Board issued an emergency rule giving the attorney general's interpretation effect. At the end of March 2020, a federal district court granted a temporary restraining order, which the Court of Appeals for the Fifth Circuit reversed. The Fifth Circuit held that Texas's abortion ban was a reasonable way to conserve medical supplies and hospital capacity. Moreover, the Fifth Circuit determined that medication abortion, which only entails taking two pills, reduces supplies of PPE because of the ultrasound and in-person consultation Texas law requires of all abortion patients. The district court granted a second temporary restraining order on April 9, 2020, permitting medication abortion and abortion for patients nearing gestational legal limit. Ultimately after another round of opinions, the Fifth Circuit reversed the second order, which resulted in the abortion suspension, with one exception, resuming. The Fifth Circuit again held that medication abortion consumed PPE, this time because providers (as other healthcare professionals) wear protective masks and gloves when

seeing patients during the pandemic. The revived suspension was short-lived, however; two days later, a new executive order took effect, and the governor's office issued a statement that abortion was excluded from the order's terms.

COVID-19 Orders that Expired or Were Replaced

Alaska's Health Mandate, issued by the governor and the Department of Public Health on April 7, 2020, declared surgical abortions "non-urgent" and ordered them postponed unless the pregnancy endangered the woman's "life or physical health." The order remained in effect until it expired May 4, 2020. Kentucky's state legislature then passed a bill to limit access to abortion services. The governor of Kentucky vetoed the bill after the legislative session.

Mississippi's governor issued an order on April 10, 2020 that delayed all non-essential elective surgeries and medical procedures, including abortion services. The ban remained in effect without challenge until an updated order issued on May 11, 2020, which allowed abortion services to resume. Iowa's governor issued an executive order on March 26, 2020 prohibiting all nonessential and elective surgeries and procedures that utilize PPE, including abortions. In lieu of a lawsuit, abortion providers and the government reached a settlement allowing abortion procedures to continue. Similarly, the Louisiana Department of Health's March 21, 2020 order postponed medical and surgical abortions for 30 days, except those (1) "to treat an emergency medical condition" or (2) "to avoid further harms from underlying condition or disease," leaving that determination to the provider's "best medical judgment." After the attorney general sent state representatives to observe abortion clinics' compliance with the order, abortion providers filed a legal challenge that was withdrawn after the parties reached a settlement that permitted abortion services to resume. In West Virginia, on March 31, 2020, the governor issued an executive order prohibiting all elective medical procedures that were not medically necessary to preserve the patient's life or long-term health, which the attorney general interpreted to include abortion services. The state's only abortion provider filed a federal lawsuit, but a new executive order on April 30, 2020 lifted the abortion suspension.

Finally, Arkansas was the state with the longest-lasting COVID-19 order limiting abortion. From April 10, 2020 until June 1, 2020, the Arkansas Department of Health banned "surgical" abortions except if necessary to protect the life or health of the patient. Providers filed for a temporary restraining order on April 13, 2020, which the district court granted. The Court of Appeals for the Eighth Circuit, however, reversed and also denied providers' request for an exception for patients approaching the gestational legal limit. The Eighth Circuit held that suspending abortion was a reasonable means to conserve hospital space and PPE, following the Fifth Circuit's reasoning described above. The state issued a modified order on April 27, 2020 allowing access to abortion services if patients had "at least one negative COVID-19 NAAT test within 48 hours prior to the beginning of the procedure." The Department of Health order was modified on May 18, 2020, extending the testing timeframe to 72 hours, and the testing requirement was lifted on June 12, 2020 when the order expired.

During the weeks of fluctuating legal status across these 12 states, patients had their appointments cancelled with a moment's notice and were turned away from clinics (Alexandria, 2020). Clinics that reopened had long waiting lists for appointments. The resulting hardships of state abortion suspensions, affirm that, for patients with delayed or denied care, abortion is an essential service.

Strain on the Healthcare System and Deepened Disparities

Suspending abortion does not conserve scarce medical resources and does not impede COVID-19's spread. Banning abortion has the net effect of a greater consumption of health resources because people will travel out of state for abortion care, self-induce terminations, or will be forced to carry pregnancies to term.

First, many people who lack access to abortion will travel to other jurisdictions to end their pregnancies, consuming the same medical resources but requiring providers in neighboring states—without the assistance of additional staff or capacity—to manage an influx of new patients (Bearak et al., 2020). Already overextended providers saw an influx of new patients. As a result, wait times and crowding increased at clinics in states neighboring those with abortion suspensions. Increased delay comes with the cost of more expensive procedures later in pregnancy or timing out of a legal abortion altogether. And to emphasize what may be obvious, during the pandemic, people who travel long distances for abortion care cannot limit social contact and take risks that could be avoided but for their state's animus for abortion rights.

People who did not or could not travel, likely terminated pregnancies by ordering online (or procured elsewhere) one or both of the pills taken in a medication abortion and taking them without physician supervision. Self-managed abortion can be effective and safe. However, it can also increase costs for the healthcare system if patients lack accurate information and adverse health consequences occur.

Finally, and perhaps most significantly, unplanned parenthood results in the consumption of healthcare resources. Continuing a pregnancy requires prenatal care that includes multiple interactions, each necessitating PPE, with healthcare professionals—far more PPE, hospital space, and healthcare professionals' time than any type of abortion. Furthermore, childbirth has steep costs and health risks, particularly for low income people and people of color. The United States has the worst maternal mortality rate in comparison to countries similarly situated; Black women are four times as likely to die in childbirth than white women (Greene Foster, 2020).

In the same vein, abortion suspensions have fallen disproportionately on people who have shouldered the hardships imposed by COVID-19—people who are unemployed or essential workers, and those who do not have access to healthcare or face other logistical challenges. These populations cannot afford the additional costs imposed by abortion suspensions, and they are people for whom COVID-19 has deepened unequal access to health resources.

Rather than suspend abortion, expanding access to medication abortion, particularly through telemedicine, could help slow COVID-19's spread. However, as the next section makes plain, longstanding regulation that contradicts medical evidence and clinical practice makes delivering medication abortion unnecessarily difficult.

The Battle over Remote Abortion Care

Abortion has been more closely regulated than comparable (and riskier) outpatient procedures well before COVID-19. Public health research makes clear that abortion-targeted laws, unlike rules for outpatient procedures with similar, or even higher risk, apply "regardless of the level of sedation or anesthesia used[] or the nature of the office intervention" (Jones et al., 2018).

Legislative efforts, in response to and before the onset of the pandemic, target medication abortion to undermine abortion rights rather than ensure patient safety or to conserve effectively health system and provider capacity. Contrary to the conclusions of the Fifth and Eighth Circuits, described above, medication abortions typically require no gown, mask, eyewear, shoe covers, or gloves; in other words, no PPE is used. Like the vast majority of terminations, medication abortion is not administered in a hospital or physician's office but in standalone clinics devoted to reproductive health services. Because the risks and complications associated with medication abortion are very low, rarely will a hospital bed be taken because of medication abortion (Upadhyay et al., 2019). Medication abortion could require no contact with healthcare providers, except that law requires it.

Legal Restrictions on Teleabortion

Despite the ease with which medication abortion can be administered, and its proven effectiveness, several states and the federal government obstruct efforts to provide remote solutions for its delivery. Medication abortions make up almost 40% of the nation's total abortions (Jones et al., 2019). In a medication abortion, which occurs during the first 10 weeks of pregnancy (or 11 weeks for off-label but accepted use), patients ingest two pills: the first drug, mifepristone, is followed by a second drug, misoprostol, taken 24–48 hours later. Federal rules prohibit dispensing the drugs through the mail or at a pharmacy. The U.S. Food and Drug Administration (FDA) restricts mifepristone under a drug safety program (a Risk Evaluation and Mitigation Strategy or REMS), which mandates, among other things, collection of the drug at a clinic, physician's office, medical center, or hospital.

Also, several states' laws impose additional restrictions beyond the REMS protocol. Eighteen states mandate that the prescribing physician be physically present when the patient collects and takes the medication (LawAtlas State Abortion Laws, 2019). The number of states mandating the physical presence of a physician during medication abortion will increase if pending state bills pass. In addition, 33 states prohibit non-physicians from administering medication abortion despite evidence that advanced practice clinicians can safely and effectively counsel patients. These laws layer on top of additional legal requirements, such as pre-termination ultrasounds and counseling. Mandatory ultrasound requirements specifically thwart teleabortion by necessitating clinic-patient contact.

Finally, nine states ban telehealth through legislation that exempts abortion from any permitted telemedicine. On the federal level, a bill before Congress, the Teleabortion Prevention Act of 2020, excludes abortion services from telehealth measures by requiring that physicians be present during terminations. At the same time, the federal government has expanded telehealth for non-abortion medical services, recognizing the importance of health care solutions that limit contact between professionals and patients (Ross, 2020). The coronavirus relief legislation issued guidelines for Medicaid and Medicare coverage of telehealth and included grants to develop telehealth practices for federally qualified health centers, rural health clinics, and hospices. Likewise, 27 states have extended telemedicine, through new legislation or executive orders, as a response to the pandemic (see Schmit et al., Chapter 16). For example, the same week that the Texas Medical Board issued an emergency rule to apply suspend abortion as non-essential care, the same board relaxed restrictions on medical consultation, treatment, and diagnosis over the Internet and telephone.

Support for Teleabortion

Research demonstrates that medication abortion, like many other healthcare procedures, can be safely and effectively administered online or over the telephone. Teleabortion could permit “no-touch” terminations, which have demonstrated effectiveness and low risk to patients suitable for remote supervision (Raymond et al., 2019). Patients who are not at risk for medical complications, are less than eight weeks pregnant, and have regular menstrual cycles may not need in-person visits or pre-termination ultrasounds. A study launched by Gynuity Health Projects (with permission from the FDA) monitored healthcare professionals providing medication abortion care by videoconference and mail. Results of the study illustrate that “direct-to-patient telemedicine abortion service was safe, effective, efficient and satisfactory” (Raymond et al., 2019). A literature review summarizes that “there is overwhelming evidence that the safety and effectiveness of medication abortion is the same whether it is provided via telemedicine or through in-person provision, as shown by a seven-year cohort study with tens of thousands of patients, systematic reviews, and an evaluation of a telemedicine abortion service across five states” (Center for Reproductive Rights & Columbia Mailman School of Public Health, 2020).

Some states, embracing this evidence, have recognized abortion as essential health care that must remain available during the national emergency. Three states explicitly protected access to abortion in executive orders, and an increasing number of health centers have relied on teleabortion, where permitted, so that eligible patients can pick up medication and self-administer while being in remote contact with their physician (Baker, 2020). As an early response to the pandemic, 21 state attorneys general wrote a letter urging the government to lift or to stop enforcing the FDA’s protocol for mifepristone (Becerra et al., 2020).

Moreover, the call for teleabortion presently is before the federal judiciary. On July 13, 2020, the US District Court of the District of Maryland issued a nationwide injunction of the REMS mifepristone protocol for the duration of COVID-19 national emergency. The court noted that the REMS restriction contradicts substantial

evidence of the drug’s safety. The protocol also unreasonably singles out mifepristone without any corresponding health benefit. Of the 20,000 drugs regulated by the FDA, mifepristone is the only one that patients must retrieve at a medical center but may self-administer without supervision. In fact, the FDA permits mailing the same compound, when not prescribed for abortion or miscarriage, to patients’ homes in higher doses and larger quantities. The effect of the REMS classification is that medication abortion cannot be mailed, excluding the possibility of telehealth for abortion. The FDA’s enforcement of the in-person requirement for mifepristone stands in stark contrast to the numerous ways the FDA (as well as other federal agencies) have encouraged telemedicine as a response to the pandemic.

The decision also details the cumulative effects of abortion restrictions based on expert testimony and public health research—that the “combination of such barriers can establish a substantial obstacle.” The court cited evidence of how the in-person requirement exacerbates the burdens already felt by those who work essential jobs or are unemployed, have lost health insurance, live in multi-generational homes, and lack transportation. The opinion highlighted that low-income patients and people of color suffer disproportionately; they are more likely to become ill, to have inadequate resources to respond to illness, and will have worse health outcomes as a result deep health inequalities. Mirroring the logistical challenges most abortion patients face, the pandemic makes arranging for childcare, transport, or time off work especially difficult.

The district court’s decision has been appealed to the Fourth Circuit, and it may come before the Supreme Court, depending on how long the national emergency lasts. 🌟

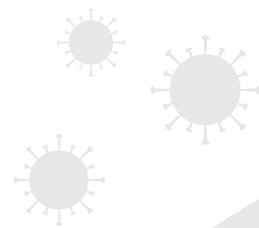
Recommendations for Action

Federal government:

- The FDA should stop enforcing the outdated REMS protocol so that:
 - Physicians no longer have to certify in a written form submitted to the drug sponsor that they have certain required qualifications;
 - Mifepristone can be dispensed outside of a hospital, clinic, or medical office, by or under the supervision of a certified healthcare provider.
- The FDA should issue guidance confirming the results of studies demonstrating medication abortion's safety and efficacy, allowing mifepristone to be ordered through mail-order prescription services and at retail pharmacies.
- Congress should enact legislation that, counter to the Teleabortion Prevention Act 2020, advances teleabortion by recognizing that medical abortion can be a health service appropriately included in plans for telemedicine's expansion.
- Congress should pass a supplemental appropriations act for the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) that does not exclude funding for teleabortion care.

State governments:

- Repeal cumbersome abortion regulations, such as waiting periods and ultrasound requirements, so that patients can avoid unnecessary visits to clinics and decrease the risk of COVID-19 exposure.
- Repeal penalties for self-managed abortion including criminal penalties for extralegal abortion.
- Repeal restrictions on telemedicine as applied to abortion, such as in-person and physician-only administration of medication abortion.
- Include medication abortion among the healthcare services subject to state efforts to expand telemedicine or to relax restrictions on telemedicine.
- Lift restrictions on telehealth modes (include telephone, audio-only communications), locations (permit use at home), delivery (allow any health care provider operating across jurisdictions) in revised state orders and legislation.



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References

- Alexandria, P. Abortion Is Available Again in Texas. But You'll Have to Get in Line. *Rewire News*. Retrieved July 28, 2020, from <https://rewire.news/article/2020/05/06/abortion-is-available-again-in-texas-but-youll-have-to-get-in-line/>
- Baker, C. N. (2020). Feminist Multi-Front Battle to End FDA's Abortion Pill Restriction. *Ms. Magazine*. Retrieved July 16, 2020, from <https://msmagazine.com/2020/05/20/feminist-multi-front-battle-to-end-fdas-abortion-pill-restriction/>
- Bearak, J., Jones, R. K., Nash, E., & Donovan, M. K. (2020). Policy Analysis: COVID-19 Abortion Bans Would Greatly Increase Driving Distances for Those Seeking Care. Retrieved July 16, 2020 from the Guttmacher Institute, <https://www.guttmacher.org/article/2020/04/covid-19-abortion-bans-would-greatly-increase-driving-distances-those-seeking-care>
- Center for Reproductive Rights & Columbia Mailman School of Public Health (2020). Expanding Telemedicine Can Ensure Abortion Access During COVID-19 Pandemic. Retrieved July 16, 2020, from <https://reproductiverights.org/sites/default/files/documents/Expanding%20Telemedicine%20Can%20Ensure%20Abortion%20Access%20During%20COVID-19%20Pandemic.pdf>
- Greene Foster, D., Antonia Biggs, M., Ralph, L., Gerdtts, C., Roberts, S., & Maria Glymour, M (2018). Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States. *American Journal of Public Health*, 108(3), 407-413.
- Jones, B. S., Daniel, S., & Cloud, L. K. (2018). State Law Approaches to Facility Regulation of Abortion and Other Office Interventions. *American Journal of Public Health*, 108(4), 486-492.
- Jones, R. K., Witwer, E., & Jerman, J. (2019). Abortion Incidence and Service Availability in the United States, 2017. Retrieved July 16, 2020 from the Guttmacher Institute, <https://www.guttmacher.org/report/abortion-incidence-service-availability-us-2017>
- LawAtlas (2019). State Abortion Laws, Medication Abortion Requirements. Retrieved July 28, 2020 from <http://lawatlas.org/datasets/medication-abortion-requirements>
- Raymond, E., Chong, E., Winikoff, B., Platais, I., Mary, M., Lotarevich, T., Castillo, P. W., Kaneshiro, B., Tschann, M., Fontanilla, T., Baldwin, M., Schnyer, A., Coplon, L., Mathieu, N., Bednarek, P., Keady, M., & Priegue, E. (2019). TelAbortion: evaluation of a direct to patient telemedicine abortion service in the United States. *Contraception*, 100(2019), 173-177.
- Ross, J. (2020). Ohio Senate Passes Bill to Ban Use of Telemedicine for Abortions. Retrieved July 16, 2020 from Jurist, <https://www.jurist.org/news/2020/03/ohio-senate-passes-bill-to-ban-use-of-telemedicine-for-abortions/>
- Sobel, L., Frederiksen, B., & Salganicoff, A. (2020). State Action to Limit Abortion Access During the COVID-19 Pandemic. Retrieved July 16, 2020 from the Kaiser Family Foundation, <https://www.kff.org/womens-health-policy/issue-brief/state-action-to-limit-abortion-access-during-the-covid-19-pandemic/>
- Upadhyay, U. D., Desai, S., Zlidar, V., Weitz, T. A., Grossman, D., Anderson, P., & Taylor, D. (2015). Incidence of Emergency Department Visits and Complications After Abortion. *Obstetrics & Gynecology*, 125(1), 175-183.
- Upadhyay, U. D., & Grossman, D. (2019). Telemedicine for Medication Abortion. *Contraception*, 100(2019), 351-353.
- Teleabortion Prevention Act of 2020, S. 3252, 116th Congress (2020), retrieved July 16, 2020, from <https://www.congress.gov/bill/116th-congress/senate-bill/3252/text>

Telehealth in the COVID-19 Pandemic

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SUMMARY. The COVID-19 pandemic highlights the value of telehealth as a public health measure by permitting health care at a distance, keeping providers and patients safe while enabling health care in strained health systems. This Chapter explores how states have acted through legislative, regulatory, and executive actions to leverage telehealth in the COVID-19 response. Congress passed three new pieces of federal telehealth legislation in response to COVID-19: The Coronavirus Aid, Relief, and Economic Security (CARES) Act, the Telehealth Services During Certain Emergency Periods Act, and the Families First Coronavirus Response Act. These new federal laws provide additional funding and regulatory flexibility for telehealth under the Medicare and TRICARE programs. Additionally, 27 states have new telehealth authorities in response to COVID-19. These new state authorities generally expand telehealth by removing regulatory barriers, authorizing more telehealth providers or telehealth modalities, and expanding telehealth coverage. This Chapter includes a number of recommendations for policymakers including addressing inequities, eliminating telehealth barriers (e.g., location requirements), authorizing additional providers and telehealth modalities, and expanding telehealth coverage.

Introduction

Defined as “the use of electronic information and telecommunication technologies to support long-distance clinical health care,” telehealth is touted as a tool to improve health care access by connecting patients with providers at a distance (HRSA, 2018; Speyer et al., 2018). Telehealth is particularly useful in rural or health care shortage areas where patients have difficulty finding a provider in their area. Telehealth also shows promise as an effective and cost-saving form of health care delivery.

Nevertheless, telehealth has challenges compared to traditional care. Telecommunication does not permit physical exams or use of some special equipment and creates technological and security issues for providers and patients (Balestra, 2018). Technology access, digital literacy, and reliable internet coverage are major barriers to telehealth that are experienced disproportionately among certain populations, particularly the elderly, persons of color, and individuals with low socioeconomic status (Velasquez & Mehrotra, 2020). Consequently, there are known disparities in telehealth usage. Unfortunately, the populations with disproportionately high telehealth barriers are many of the same populations at the highest risk of COVID-19.

More troubling, while telehealth visits have increased substantially during the COVID-19 emergency, disparities are widening. Evidence suggests that the proportion of the elderly, persons of color, and

individuals with low socioeconomic status receiving telehealth services has actually decreased significantly during the COVID-19 response (Nouri et al., 2020). This worrisome evidence suggests that health inequities among these populations are likely to increase. These inequities might even be exacerbated if health care systems and providers prioritize limited telehealth capacity on those patients that can provide the highest reimbursement rates (i.e., those with private health insurance) (Clair et al., 2020)

These and other issues provide justification for governmental regulation to promote safe and effective health care. State and federal laws, however, can be both facilitators and barriers to telehealth.

Licensure and scope of practice laws determine whether a health care provider can provide telehealth services (CCHP, 2020; Schmit et al., 2019). For example, some states restrict the ability of non-physician providers (e.g., nurse practitioners, licensed professional counselors) to provide telehealth services. Interstate scope of practice variation is cited as a major barrier to interjurisdictional telehealth (Sodhi, 2020).

Laws regulating Medicare, Medicaid, and private health plans establish rules and requirements for paying for telehealth services, fundamentally shaping service delivery (Mehrotra et al., 2017; Sodhi, 2020). Some states permit Medicaid and private health plans to reimburse telehealth services at lower rates than comparable

in-person services while other states require payment parity between telehealth and in-person services. Parity laws provide a monetary incentive for providers to offer telehealth services, but prevent health care payers from taking advantage of telehealth's cost-saving potential (Turner Lee et al., 2020). Some laws impose barriers for new telehealth patients (e.g., requiring an initial in-person visit). Restrictive telehealth payment laws are cited as a barrier to telehealth adoption (Mehrotra et al., 2017). However, other laws can facilitate telehealth use (e.g., laws requiring private health plans to cover telehealth) (Adler-Milstein et al., 2014; Sodhi, 2020).

Laws also define which telecommunication modalities qualify as a telehealth service both for practice and reimbursement (Bagchi, 2020). Prior to COVID-19, all states permitted some form of synchronous (i.e., real-time) video telehealth (CCHP, 2020). Asynchronous (i.e., store-and-forward) telehealth was less commonly permitted by states, and audio-only communication was rarely permitted among states (see Iowa, Maine, Oregon). Laws that limit telehealth services to synchronous video communications challenge patients without access to technology (e.g., computer, smart phone) or broadband internet access (Bagchi, 2020).

In the context of the COVID-19 pandemic, telehealth has transformed from a tool promoting access and convenience to a vital public health measure. COVID-19 did not magically erase the existing endemic health issues, and it certainly exacerbated many (Sherrard-Smith et al., 2020; Stop TB Partnership, 2020). Patients with chronic conditions still need prescriptions and continuing care. Patients with acute conditions still need access to care and consultation. Mental and behavioral health issues still need attention and may be magnified by increased isolation. When preventative health care services are not utilized or accessible, the system is forced to respond to emergencies, progressive disease states, and skyrocketing costs.

For many governments, telehealth became a tool to promote physical distancing, enabling providers to see patients and enabling patients to seek care without exposing themselves or others to infection risk. Consequently, telehealth is a critical tool for enabling the continued delivery of health care services while simultaneously mitigating COVID-19 risks.

Policy decisions to expand telehealth also have economic drivers. Stay-at-home orders and restrictions on some procedures drastically reduced patient volumes for many health care providers. Telehealth provided a means to continue providing health care services while minimizing financial losses. Similarly, laws limiting patient out-of-pocket expenses for telehealth services might encourage patients to continue to seek needed services in a new way (i.e., telehealth) during the pandemic.

As policymakers make changes to telehealth laws to respond to the COVID-19 emergency, it is essential that these new authorities clearly communicate what is and is not permitted. Emergency response challenges both policymakers and health care providers. It can be difficult to understand what legal authorities must be added or removed in order to respond appropriately to a rapidly evolving emergency. In some cases, new telehealth legal provisions

created ambiguity and uncertainty for health care providers. For example, Oklahoma Executive Order 2020-13 attempted to remove a telehealth barrier for new patients by removing a requirement for a preexisting patient relationship but kept the patient relationship requirement for prescribing controlled substances. In fact, Oklahoma's laws did not have a general requirement for a preexisting relationship; the requirement only applied to prescribing controlled substances. Subsequent amended executive orders clarified this provision, rendering the entire provision pointless. Similarly, a number of states issued executive orders allowing providers to use telehealth or to use a new mode of telehealth (e.g., store-and-forward) that was already permitted in existing authorities. Ambiguity in new emergency authorities creates doubt for health care providers and might make them more reluctant to begin offering new telehealth services or telehealth through new modalities. Clarity is especially important for providers hesitant to invest the time, energy, and monetary resources to identify new technology and create new workflows to offer new telehealth services without any long-term policy guarantees post-COVID-19.

Assessment Federal Actions

The federal government enacted three new pieces of legislation relating to telehealth in response to COVID-19: The Coronavirus Aid, Relief, and Economic Security (CARES) Act; Telehealth Services During Certain Emergency Periods Act of 2020 (passed as part of the Coronavirus Preparedness and Response Supplemental Appropriations Act); and the Families First Coronavirus Response Act.

The Telehealth Services During Certain Emergency Periods Act of 2020 (later amended by the Families First Coronavirus Response Act and the CARES Act) provides the secretary of Health and Human Services (HHS) the authority to waive or modify Medicare requirements for telehealth services provided during the COVID-19 emergency period.

The CARES Act, the most substantial federal telehealth legislation in response to COVID-19, has a number of provisions that affect telehealth services. This Act introduced new telehealth grants and appropriations, including providing \$200 million to the Federal Communications Commission to remove some technical barriers to telehealth utilization by supporting telecommunications and information services and supplying needed devices and equipment; \$1 billion to Indian Health Services, some of which can be used to increase telehealth access and use in tribal communities; and \$27 billion to the Public Health and Social Services Emergency Fund for the COVID-19 response, including telehealth. Section 3212 of the CARES Act also expanded eligibility for some existing grants, including adding substance abuse disorder treatment as an eligible telehealth application and permitting for-profit entities to apply for telehealth grants.

The CARES Act also contains a number of provisions that permit specific telehealth applications. For example, Section 3706 of the CARES Act allows telehealth to be used in place of a face-to-face

encounter when certifying a patient for hospice care. The Act also expands tele-mental health services to veterans (prioritizing high-risk veterans), and requires the U.S Department of Veterans Affairs (VA) to provide telehealth capabilities to case managers for homeless veterans.

Congress also included a number of provisions within the CARES Act to create regulatory flexibility for telehealth in respect to the Medicaid program requirements. For example, Section 3704 of the CARES Act promotes the use of telehealth in Federally Qualified Health Centers and includes a special payment rule that ties payment amounts to the national average payments for comparable services. Additionally, Section 3701 of the CARES Act allows High Deductible Health Plans (HDHP) (regulated by the Internal Revenue Service under the Affordable Care Act) to provide coverage for telehealth services without a deductible without losing their status as a HDHP. The Centers for Medicare and Medicaid Services (CMS) has used its Section 1135 waiver authority to expand telehealth coverage and is using a subregulatory process to make coverage changes (CMS, 2020a, 2020b; I. Lee et al., 2020). CMS revised existing Medicare requirements for patient supervision to permit the use of telehealth in place of in-person visits (CMS, 2020a, 2020b). CMS expanded access to telehealth services by temporarily lifting the previously restrictive location requirements, and permitting beneficiaries to receive telehealth in any location, including their homes. Additionally, CMS authorized more health care providers and more telehealth services to be reimbursed via Medicare, including physical therapy, occupational therapy, and speech pathology services (CMS, 2020a, 2020b).

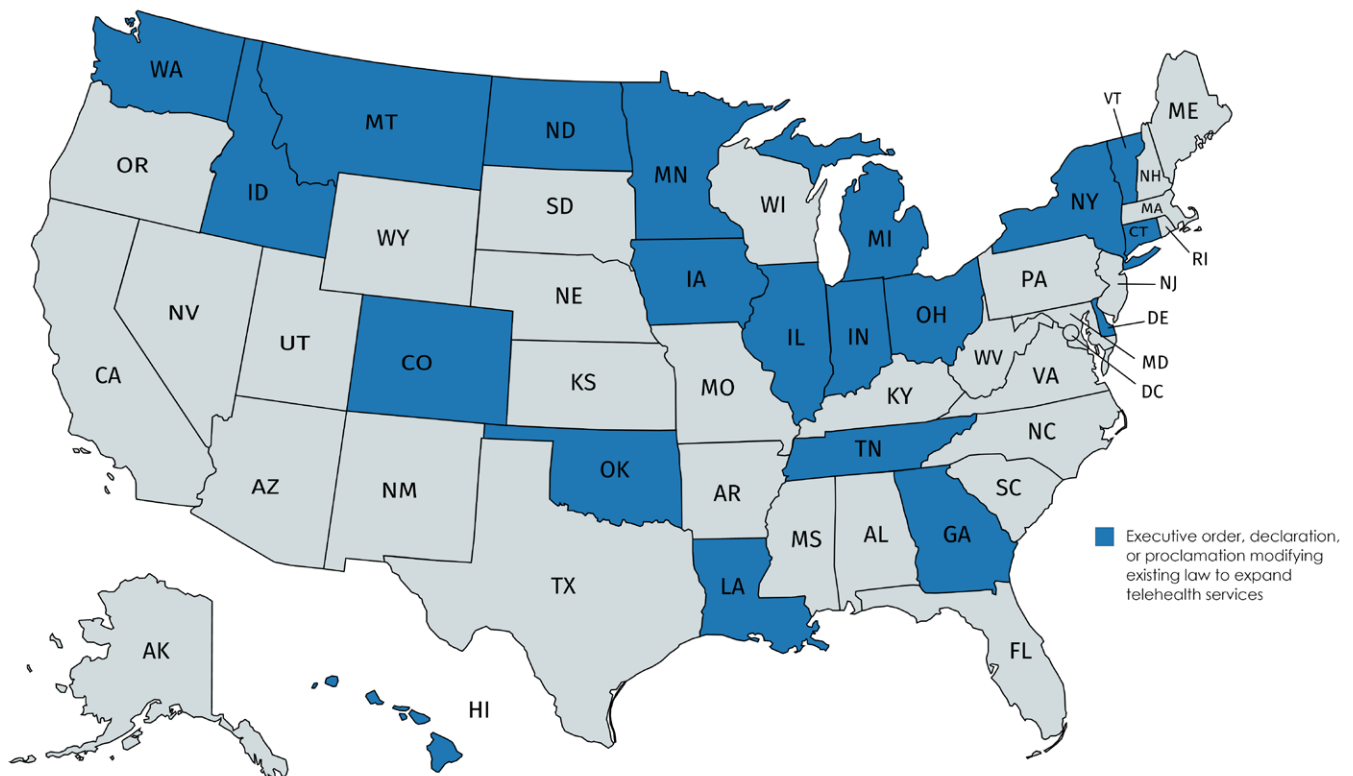
Regulatory amendments to the TRICARE program make telehealth more available, including permitting telehealth services over the phone and waiving out-of-pocket expenses for telehealth (i.e., copayments and deductibles). Similarly, the VA promulgated a regulation permitting home visits to occur via telehealth.

On March 20, 2020 the Office of Civil Rights (OCR) in HHS announced that it was not going to enforce the Health Insurance Portability and Accountability Act (HIPAA) violations against providers using telehealth in “good faith” during the COVID-19 emergency. This announcement gave providers without existing telehealth platforms the freedom to use publicly available telecommunication platforms (e.g., Zoom, Apple FaceTime, Google Hangouts) so long as the platform was not public facing (e.g., Twitter, TikTok, Facebook Live). This move aimed to give health care providers leeway to adapt to a rapidly changing environment without fear that they would face HIPAA’s steep penalties. Still, providers wary of telehealth security and privacy pre-COVID-19 might not be assuaged by the OCR decision. Without guarantees of long-term allowances for less secure platforms, providers may be hesitant to make significant (and often costly) changes in their practice or organization.

State Actions

As of May 18, 2020, 27 states implemented new authorities relating to telehealth in response to COVID-19. Five states enacted new legislation (ID, MI, PA, VT, WA), nine states promulgated emergency regulations (CO, IL, LA, NV, NY, OH, OR, TX, WA), and 23 states issued an executive order, declaration, or proclamation relating

Figure 16.1. States with executive orders, declarations, or proclamations modifying existing laws to expand telehealth.



to telehealth in response to COVID-19 (AR, CO, CT, DE, GA, HI, ID, IL, IN, IA, LA, MI, MN, MT, NH, NJ, NY, ND, OH, OK, TN, VT, WA). Twenty states had executive orders, declarations, or proclamations modifying existing laws to expand telehealth (Figure 16.1).

State Actions Addressing Barriers to Telehealth Access and Care.

Eleven states expressly encouraged telehealth use (Table 16.1). Ten states removed telehealth barriers for new patients (e.g., prior in-person visit requirements)(AR, CT, DE, HI, LA, MI, MN, MT, NY, OH). Seven states authorized prescribing controlled substances via telehealth without a prior in-person encounter. Four states expanded acceptable telehealth locations to permit providers and patients to interact from a safe location (e.g., their homes), supporting physical-distancing public health measures.

State Actions Addressing Telehealth Coverage and Cost. States can address telehealth financial barriers by requiring health care coverage of appropriate services and reducing out-of-pocket expenses. Expanding telehealth coverage and reducing out-of-pocket expenses incentivizes telehealth and mitigates exacerbating existing and emerging health issues during the COVID-19 response. Seven states expanded Medicaid coverage, 14 states expanded private health insurance coverage, and four states expanded workers’ compensation coverage for telehealth services (Figure 16.2). Eliminating out-of-pocket expenses also helps providers rapidly implement telehealth services because collecting copays at a distance requires new infrastructure and workflows. These demands may discourage organizations from offering new telehealth services. Moreover, incentivizing telehealth usage may drive down health care costs by normalizing a cost-effective health care service. Two states have acted to limit Medicaid out-of-pocket expenses, and seven states have limited private insurance out-of-pocket expenses for telehealth services (Figure 16.3).

Prior to COVID-19 many states had adopted parity laws requiring payment for telehealth services at the same amount as comparable in-person services. There are arguments for and against requiring telehealth parity (e.g., promoting telehealth versus limiting telehealth’s cost-saving potential). During the COVID-19 response, some health care providers are seeing precipitous decreases in patient volumes with substantially reduced revenues. Requiring telehealth parity has the dual function of encouraging telehealth adoption by providers and helping providers weather the current financial challenges (Shachar et al., 2020). In response to COVID-19, states added legal authorities requiring telehealth parity for Medicaid (MT, NH, OR) and workers’ compensation (CO, TN, TX). Seven states added legal authorities requiring parity for private health plans (CO, IA, MT, NH, TX, VT, WA); however, all these states had some form of parity prior to the COVID-19 response (CCHP, 2020).

Telehealth Modalities. Strict telehealth technology requirements pose inequitable burdens on at-risk populations without access to a device capable of synchronous video communication. Without more accessible modes of telehealth (i.e., telephone, email), some populations will lose health care access during the COVID-19 response, exacerbating health inequities and forcing care in riskier health care contexts (e.g., emergency rooms).

Table 16.1: State Actions Relating to the Use of Telehealth in the Response to COVID-19

STATE	ENCOURAGED TELEHEALTH	EXPANDED TELEHEALTH LOCATIONS	CONTROLLED SUBSTANCES RX AUTHORIZED
AR			
CO			
CT		HC	
DE			
GA			
HI			Yes
ID			
IL	Yes		
IN	Yes		Yes
IA			Yes
LA	Yes		Yes
MI	Yes		Yes
MN	Yes		
MT	Yes	PT, HC	
NV			
NH	Yes	PT	
NJ	Yes		Yes
NY			
ND			
OH		PT	
OK	Yes		
OR			
PA			
TN	Yes		Yes
TX			
VT			
WA	Yes		

PT - Indicates expanded telehealth locations for patients

HC - Indicates expanded telehealth for health care providers

Figure 16.2. States Expanding Telehealth Coverage in Response to COVID-19

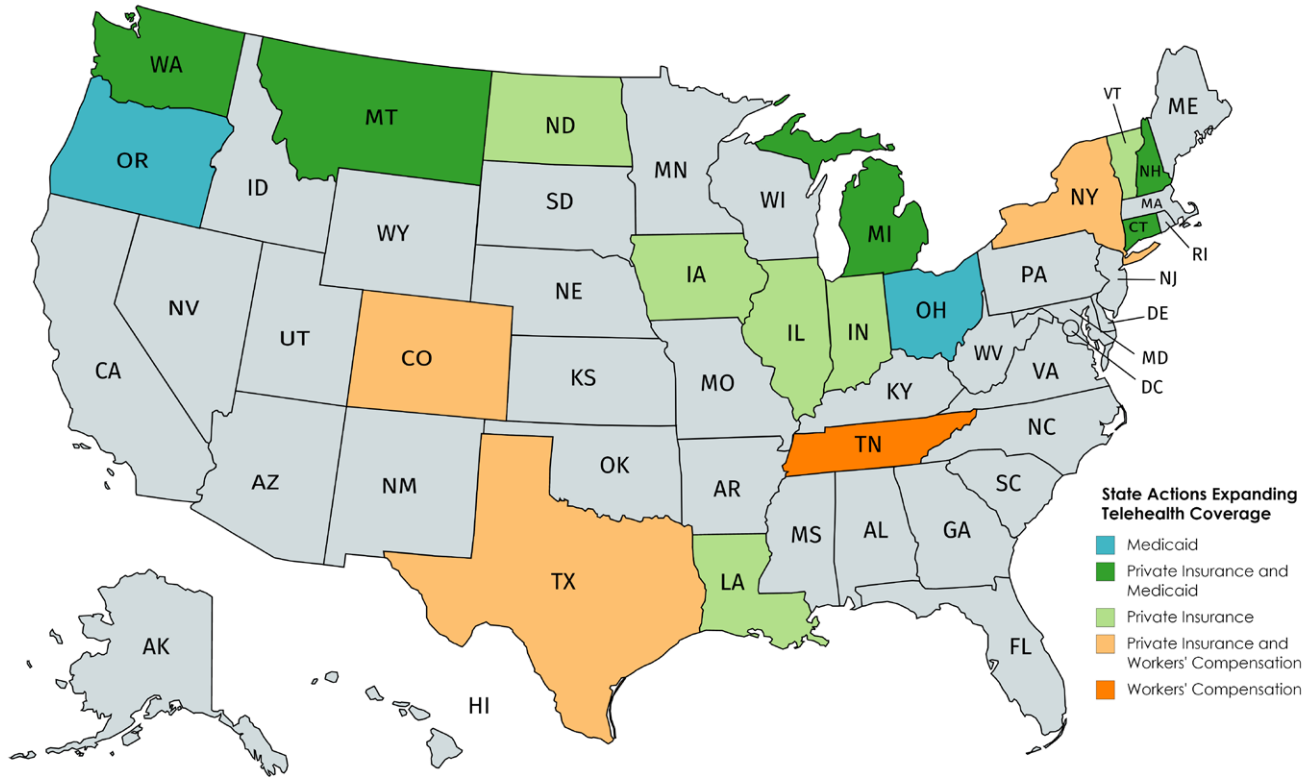
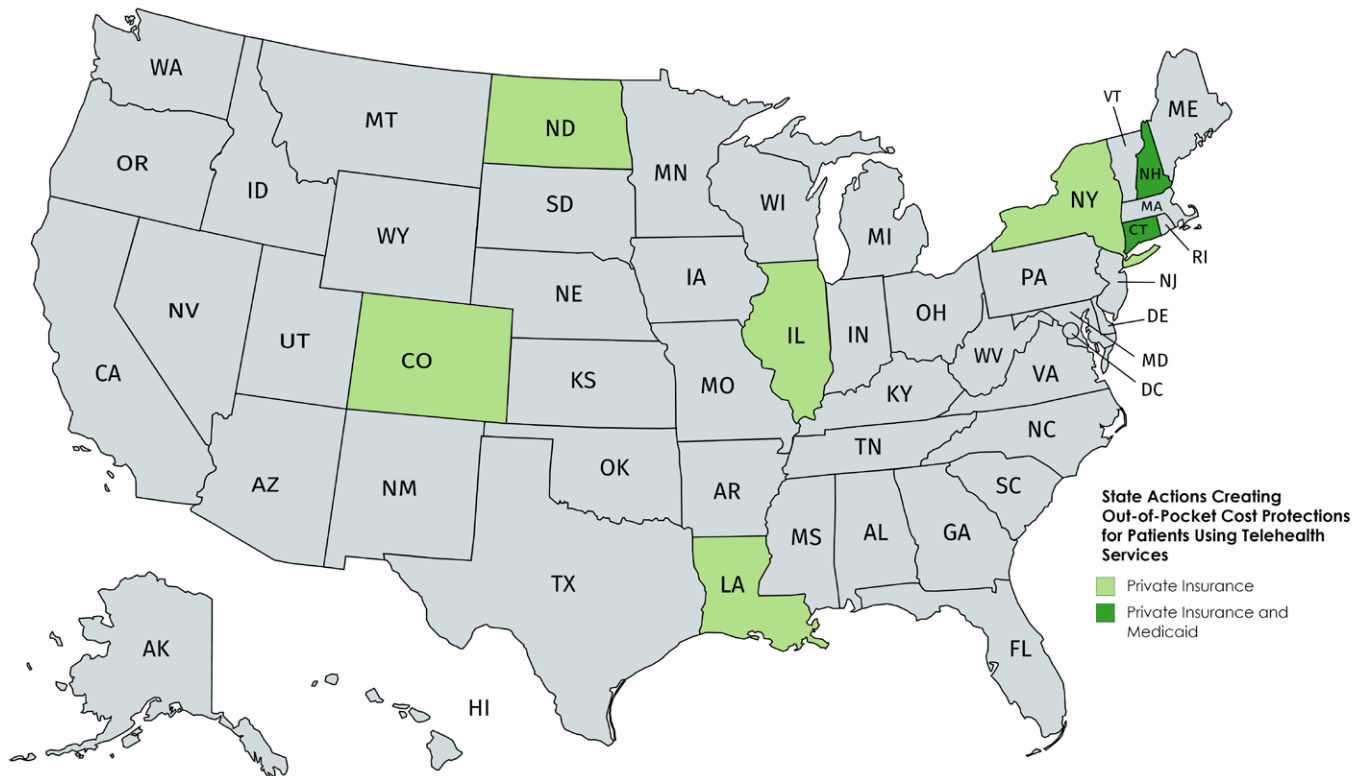


Figure 16.3. State actions creating out-of-pocket cost protections for telehealth services



In response to COVID-19, 16 states expanded permissible telehealth modalities. Eleven added asynchronous methods (CO, CT, DE, IL, IN, MI, MT, NH, OH, OR, VT); 15 added audio-only (e.g., phone) communications (CO, CT, DE, HI, IL, IN, IA, LA, MI, MT, NH, ND, OH, OR, VT); six added text or email communications (CO, MT, NH, OH, OR, VT); and six states added broad permissive language for “other” modalities (CO, IL, MT, NH, NJ, OR) (Table 16.2).

Telehealth Providers. Fourteen states have new authorities that describe or expand the provider types that can provide telehealth (Table 16.2), although many were redundant to existing laws.

There is a strong argument that states should permit any telehealth service that can meet the same standard of care as the comparable in-person service. In the context of COVID-19 – where in-person visits pose additional risks for providers and patients and delaying care exacerbates health issues – states should consider permitting telehealth services where providers can meet an acceptable level of care. In determining acceptable levels of care, policymakers should consider the risk of harm from a comparable in-person visit and risk of harm from delaying the service until after the COVID-19 emergency.

Interjurisdictional Telehealth. State variation in scope of practice and licensure regulations impedes interjurisdictional telehealth practice. Minimizing this barrier will enable providers to quickly mobilize to provide care in new jurisdictions stressed by COVID-19.

Fifteen states expanded the authority to provide telehealth across state lines. Three states (DE, NH, OH) gave in-state providers the authority to provide telehealth to out-of-state patients. Fourteen states granted out-of-state health care professionals authority to provide telehealth to in-state patients, including out-of-state primary care providers (HI, IA), specialists (CT, IA), mental or behavioral health providers (CO, CT, HI, IA, MN), and physical, occupational, or speech therapists (CT, IA). Nine states (DE, GA, LA, MI, MT, NH, ND, OK, TN) provided a broad authorization for out-of-state providers (e.g., “licensed health professionals in good standing”). 🌞

Table 16.2. State Actions Expanding Modes of Telehealth Delivery Practice and Additional Telehealth Providers Eligible for Payment or Reimbursement

STATE	STORE AND FORWARD	AUDIO-ONLY	TEXT/EMAIL	OTHER	NON-PHYSICIAN	SPECIALIST	MENTAL/ BEHAVIORAL HEALTH (NON-PHYSICIAN)	THERAPISTS*	BROAD
AR							Yes		
CO	Yes(PI)	Yes(PI)	Yes(PI)	Yes(PI)					
CT	Yes(M)(PI)	Yes(M)(PI)				Yes	Yes	Yes	
DE	Yes	Yes							
GA									
HI		Yes			Yes		Yes		
ID									
IL	Yes(PI)	Yes(PI)		Yes(PI)	Yes(PI)	Yes(PI)	Yes(PI)	Yes(PI)	
IN	Yes(PI)	Yes(PI)						Yes	
IA		Yes(PI)							
LA		Yes(PI)					Yes(PI)		
MI	Yes(M)(PI)	Yes(M)(PI)							Yes(M)(PI)
MN									
MT	Yes(M)(PI)	Yes(M)(PI)	Yes(M)(PI)	Yes(M)(PI)					
NV									
NH	Yes(M)(PI)	Yes(M)(PI)	Yes(M)(PI)	Yes(M)(PI)	Yes	Yes	Yes(M)(PI)	Yes	Yes(M)(PI)
NJ				Yes					
NY					Yes		Yes		
ND		Yes(PI)							
OH	Yes(M)	Yes(M)	Yes(M)		Yes(M)	Yes(M)	Yes(M)	Yes(M)	
OK									
OR	Yes(M)	Yes(M)	Yes(M)	Yes(M)			Yes(M)		
PA									
TN					Yes	Yes	Yes	Yes(WC)	Yes
TX					Yes(PI)	Yes(PI)	Yes(PI)		Yes(PI)
VT	Yes(PI)	Yes(PI)	Yes(PI)			Yes(PI)			
WA									

* Includes physical, occupational, speech therapists, etc., but does not include mental or behavioral health therapists.

(M) - Indicates at least one provision relating to Medicaid

(PI) - Indicates at least one provision relating to private health insurance

(WC) - Indicates at least one provision relating to Workers' Compensation

Recommendations for Action

The physical distancing measures needed to limit COVID-19 spread also pose a substantial barrier to preventative services and general health care. Without such care, existing and emerging health conditions are likely to worsen, creating more harmful and expensive problems in the future (Sherrard-Smith et al., 2020; Stop TB Partnership, 2020). Telehealth must be fully leveraged to provide care while limiting opportunities for COVID-19 spread. Consequently, states should consider policy options to expand telehealth access and utilization even if those options allow less than ideal health care (e.g., telehealth over the phone). Some care is better than no care. Above all, governments should ensure that laws and the emergency modifications to those laws are clear to health care providers and the public.

Federal government:

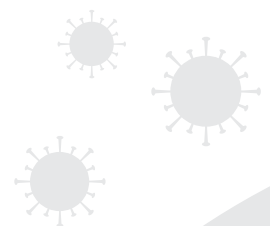
To reap the benefits of telehealth during the COVID-19 pandemic and after:

- Congress should enact legislation:
 - o Permitting Medicare and Medicaid reimbursement for patient training and education relating to telehealth digital literacy and encourage providers to target populations with known disparities in telehealth services.
 - o Permanently extending the telehealth Medicare expansion permitting patients to receive telehealth from new locations, including rural health clinics, Federally Qualified Health Centers and patients' homes.
 - o Permanently extending Medicare coverage of telehealth services that can be delivered to the same standard of care as comparable in-person services.
 - o Permanently reducing or eliminating copayments and other out-of-pocket expenses for telehealth services that have demonstrated cost-savings compared to their in-person equivalent service.
 - o Establishing mechanisms and funding for improving access to telehealth-capable devices for underserved and vulnerable populations.
- CMS should reduce or eliminate copayments and other out-of-pocket expenses for appropriate telehealth services during the COVID-19 response.
- HHS and CDC should monitor telehealth policy changes for inequitable outcomes, especially in vulnerable populations.

State governments:

To reap the benefits of telehealth during the COVID-19 pandemic and after:

- Legislatures should:
 - o Lift restrictions on telehealth locations to permit both providers and patients to use telehealth from a safe location, including their homes.
 - o Limit out-of-pocket expenses by restricting or reducing cost-sharing (e.g., co-pays, deductibles) for telehealth services.
 - o Expand coverage of telehealth services provided by Medicaid and private health plans.
- Governors and state agencies should use their emergency powers during COVID-19 to
 - o Permit new modes of telehealth, including asynchronous, store-and-forward, audio-only (e.g., telephone), and secure messaging/email.
 - o Permit any health care provider to use telehealth for health care services if those services can be delivered to an acceptable level of care.
 - o Permit out-of-state health professionals that are licensed and in good standing in their home states to practice telehealth within their jurisdiction.
- Governors and state agencies should vigorously implement telehealth parity laws to support health care providers with falling patient volumes during the COVID-19 response.



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References

- Adler-Milstein, J., Kvedar, J., & Bates, D. W. (2014). Telehealth Among US Hospitals: Several Factors, Including State Reimbursement and Licensure Policies, Influence Adoption. *Health Affairs*, 33(2), 207-215.
- Bagchi, A. D. (2020). Expansion of Telehealth Across the Rural-Urban Continuum. *State and Local Government Review*, 0160323X2092905.
- Balestra, M. (2018). Telehealth and Legal Implications for Nurse Practitioners. *Journal for Nurse Practitioners*, 14(1), 33-39.
- Center for Connected Health Policy (CCHP) (2020). *State Telehealth Laws and Reimbursement Policies, Spring 2020*. Retrieved August 1, 2020, from https://www.cchpca.org/sites/default/files/2020-05/CCHP_%2050_STATE_REPORT_SPRING_2020_FINAL.pdf
- Centers for Medicare & Medicaid Services (CMSa) (2020). *Medicare Telemedicine Health Care Provider Fact Sheet*. Retrieved July 16, 2020, from https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet?inf_contact_key=38ca3f198618fc3aeba4091611f5b055680f8914173f9191b1c0223e68310bb1
- Centers for Medicare & Medicaid Services (CMSb) (2020). COVID-19: President Trump Expands Telehealth Benefits for Medicare Beneficiaries During COVID-19 Outbreak. Retrieved August 1, 2020, from <https://www.cms.gov/outreach-and-education/outreachffsp/rovp/rovp-provider-partnership-email-archive/2020-03-17>
- Clair, M., Clair, B. W., & Clair, W. K. (2020). Done Poorly, the Rise of Telehealth Could Widen Health Disparities. *STAT*. Retrieved August 1, 2020, from <https://www.statnews.com/2020/06/26/unless-its-done-carefully-the-rise-of-telehealth-could-widen-health-disparities/>
- Health Resources & Services Administration (HRSA) (2018). *Telehealth Programs*. Retrieved August 1, 2020, from <https://www.hrsa.gov/rural-health/telehealth/index.html>
- Lee, I., Kovarik, C., Tejasvi, T., Pizarro, M., & Lipoff, J. B. (2020). Telehealth: Helping Your Patients and Practice Survive and Thrive during the COVID-19 Crisis with Rapid Quality Implementation. *Journal of the American Academy of Dermatology*, 82(5), 1213-1214.
- Mehrotra, A., Huskamp, H. A., Souza, J., Uscher-Pines, L., Rose, S., Landon, B. E., Jena, A. B., & Busch, A. B. (2017). Rapid Growth In Mental Health Telemedicine Use Among Rural Medicare Beneficiaries, Wide Variation Across States. *Health Affairs*, 36(5), 909-917.
- Nouri, S., Khoong, E. C., Lyles, C., & Karliner, Leah MD, M. (2020). Addressing Equity in Telemedicine for Chronic Disease Management During the Covid-19 Pandemic. Retrieved August 1, 2020 from *NEJM Catalyst*, <https://catalyst.nejm.org/doi/full/10.1056/CAT.20.0123>
- Schmit, C. D., Ferdinand, A. O., Callaghan, T., Kageyama, M., Khodakarami, N., & Morrissey, M. A. (2019). The Development of Telehealth Laws in the U.S. from 2008 to 2015: A Legal Landscape, Policy Brief. Retrieved August 1, 2020 from Southwest Rural Health Research Center, <https://srhrc.tamhsc.edu/docs/srhrc-pb10-schmit-telehealth.pdf>
- Shachar, C., Engel, J., & Elwyn, G. (2020). Implications for Telehealth in a Postpandemic Future: Regulatory and Privacy Issues. *Journal of the American Medical Association*, 323(23), 2375-2376.
- Sherrard-Smith, E., Hogan, A. B., Hamlet, A., Watson, O., Whittaker, C., Winskill, P., Verity, R., Lambert, B., Cairns, M., Okell, L., Slater, H., Ghani, A. C., Walker, P. G. T., & Churcher, T. S. (2020). Report 18 - The Potential Public Health Impact of COVID-19 on Malaria in Africa. Retrieved August 1, 2020 from Imperial College London, <https://www.imperial.ac.uk/mrc-global-infectious-disease-analysis/covid-19/report-18-malaria/>
- Sodhi, M. (2020). Telehealth Policies Impacting Federally Qualified Health Centers in Face of COVID-19. *Journal of Rural Health*. Retrieved August 1, 2020, from <https://doi.org/10.1111/jrh.12445>

Speyer, R., Denman, D., Wilkes-Gillan, S., Chen, Y., Bogaardt, H., Kim, J., Heckathorn, D., & Cordier, R. (2018). Effects of Telehealth by Allied Health Professionals and Nurses in Rural and Remote Areas: A Systematic Review and Meta-analysis. *Journal of Rehabilitation Medicine*, 50(3), 225-235.

Stop TB Partnership. (2020). The Potential Impact of the COVID-19 Response on Tuberculosis in High-Burden Countries: A Modelling Analysis. Retrieved July 16, 2020, from http://www.stoptb.org/assets/documents/news/Modeling%20Report_1%20May%202020_FINAL.pdf

Turner Lee, N., Karsten, J., & Roberts, J. (2020). Removing Regulatory Barriers to Telehealth Before and After COVID-19. Retrieved July 16, 2020 from Brookings Institute, from https://www.brookings.edu/wp-content/uploads/2020/05/Removing-barriers-to-telehealth-before-and-after-COVID-19_PDF.pdf

Velasquez, D., & Mehrotra, A. (2020). Ensuring the Growth of Telehealth During COVID-19 Does Not Exacerbate Disparities in Care. *Health Affairs Blog*. Retrieved August 1, 2020, from <https://www.healthaffairs.org/do/10.1377/hblog20200505.591306/full/>

Access to Treatment for Individuals with Opioid Use Disorder

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SUMMARY. The United States is currently facing two severe public health emergencies: COVID-19 and the continuing epidemic of preventable opioid-related harm. While these epidemics share some similarities, there is one key difference: while there are currently no approved pharmaceutical treatments for the novel coronavirus, highly effective medications to treat opioid use disorder (OUD) have existed for decades. Despite their proven efficacy, access to these medications has long been limited by federal and state laws, limitations that disproportionately impact those who are made particularly vulnerable by structural factors including economic injustice and structural racism. In response to the COVID-19 epidemic, the U.S. Drug Enforcement Administration and other federal agencies have taken steps to temporarily remove some legal and regulatory barriers to these medications. These changes are not comprehensive, and most are tied to the COVID-19 public health emergency declaration. The epidemic of opioid-related harm will not end when the new coronavirus is controlled or the related emergency declaration expires. Indeed, it seems likely that steps taken to attempt to control the virus' spread may result in an even more unhealthy risk environment for people with OUD, with a resulting increase in treatment need. This Chapter briefly highlights the potential positive impact of increased access to OUD treatment, current changes to increase access to that treatment, and recommendations for making those changes permanent.

Introduction

Opioids, either alone or in combination with other substances, have killed over half a million Americans over the past 15 years – including nearly 48,000 in 2018 alone (Wilson et al., 2020). The number of Americans who use heroin more than doubled from 2002 to 2016, and an estimated two million Americans meet the criteria for opioid use disorder (OUD).

Federal and state laws, even those facially designed to provide support for individuals with OUD, often act as structural barriers to evidence-based prevention and treatment, and in many cases perpetuate and amplify stigma-driven responses to addiction and people with OUD. This is particularly true for individuals made vulnerable by economic deprivation, structural racism, and related social determinants of health. Outside of the criminal context, which systematically harms and disenfranchises already vulnerable individuals, the most poignant example of the negative impact of law on the health of people who use drugs (PWUD) is barriers to OUD treatment.

Medications for OUD have existed for decades. The most effective of these medications, methadone and buprenorphine, are referred to as opioid agonist treatment (OAT) because they activate or

partially activate opioid receptors. These medications significantly reduce many of the potential harms associated with OUD including relapse and bloodborne disease risk. Perhaps most importantly, treatment with either medication reduces both overdose-related and all-cause mortality risk in opioid-dependent individuals by approximately 50% (Sordo et al., 2017).

Because of their effectiveness and relative safety, the National Academies of Sciences, Engineering, and Medicine has declared that “[w]ithholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment” (Leshner & Dzau, 2019), and the secretary of Health and Human Services (HHS) has noted that attempting to treat OUD without OAT is “like trying to treat an infection without antibiotics” (Roubein, 2018).

Despite this rhetorical support from expert organizations and federal officials, unduly restrictive federal, state, and local laws and policies significantly impede access to OAT. While these legal and policy barriers are harmful in normal times, COVID-19 has compounded the risks to people with OUD, particularly for high-risk individuals. Overdose rates appear to be increasing, likely due to

complications arising from the novel coronavirus and efforts taken to contain it. The offices of many clinicians, treatment programs, and harm reduction services have had to close or significantly reduce their hours due to lockdowns and social distancing requirements, and disruptions to normal routines and increased social isolation may increase the risk of returning to drug use for people in recovery. Many people who previously used drugs with other individuals who would be able to respond in an overdose emergency are now using alone, dramatically increasing the risk of fatal overdose.

Legal Barriers to Opioid Use Disorder Treatment

Legal barriers to OAT are many and varied. Although methadone prescribed for pain is subject only to the restrictions that apply to all controlled substances, federal law imposes a number of additional limitations when it is used for OUD treatment. These restrictions begin with limits on which patients may receive the medication. Instead of deferring to the expertise of the prescriber, as is done with nearly every other medication, federal law limits the pool of patients who may receive methadone for OAT. To be considered for treatment, most individuals must have been addicted to an opioid for at least one year and have received a full medical evaluation prior to receiving treatment. Federal law also limits the dosage that patients can receive, regardless of the prescriber's determination of their clinical need (Davis & Carr, 2019).

Moreover, federal law strictly regulates the provision of the medication itself. Unlike most drugs, which can be dispensed at any licensed pharmacy, only federally certified opioid treatment programs (OTP) may dispense methadone for OAT, and practitioners providing it must obtain an annual registration from the federal Drug Enforcement Agency (DEA). OTPs may provide methadone only in oral form, and patients generally must ingest it under the supervision of OTP staff. Although "take home" doses are permissible, the terms under which patients are trusted with their own prescribed medication are set not by the treatment team but by federal law. These restrictions persist despite little evidence they reduce harm, and some evidence that they increase it. For example, requirements for daily dosing disproportionately harm individuals without reliable transportation and make it nearly impossible for individuals who work non-standard shifts to access methadone treatment.

Several states, including many of those with a considerable population of people with OUD, have created additional barriers to accessing methadone for OAT. For example, Georgia law limits each region of the state to a maximum of four licensed methadone programs and West Virginia has a blanket moratorium on the establishment of new OTPs (Davis & Carr, 2019). Localities often impose additional restrictions on OTPs, most notably through the use of zoning restrictions. Although several federal appellate courts have ruled that some laws that restrict the siting of OTPs violate the Americans with Disabilities Act, many states and localities implicitly or explicitly limit where they can be located – often pushing them far away from where most people live and into areas that are difficult to access via public transportation.

Federal restrictions on buprenorphine prescribed for OUD, while less severe than those imposed on methadone, also serve to

ensure that some people who would benefit from the medication are left to suffer without (Davis & Carr, 2017). Perhaps the most important of these is that only physicians and certain other health professionals who have received a federal "waiver" are permitted to prescribe buprenorphine for OUD. To qualify for a waiver, physicians must either hold a certification in addiction medicine or complete specific training, which usually includes an eight-hour series of instruction. The non-physician prescribers who can become waived (not all may do so; that too is limited by federal law) must complete 24-hours of training. Federal law also limits the number of patients a waived provider may treat. Most providers are limited to 30 or 100 patients, although some may treat up to 275.

These limitations conspire to artificially reduce the number of providers who offer the medication, as well as the patients who can benefit from it. In 2016, fewer than 30,000 doctors were waived, leaving nearly half of America's 3,100 counties, including over 60% of rural counties, without a single physician authorized to prescribe the medication (Andrilla et al., 2017). They also contribute to severe racial disparities in treatment access: despite similar prevalence of OUD among Black and white adults, from 2012 to 2015 white patients were almost 35 times more likely to have a buprenorphine-related office visit compared to Black patients (Lagisetty et al., 2019).

Access to buprenorphine is also limited by the Ryan Haight Act, which permits controlled substances to be initially prescribed, in most instances, only after the prescriber has conducted an in-person examination of the potential patient ("Controlled Substances Dispensed by Means of the Internet," 2020). This requirement, which was designed to target illicit internet pharmacies, creates nearly insurmountable barriers for individuals who would benefit from buprenorphine treatment but are unable to meet with a waived provider in person to begin therapy. This restriction falls particularly hard on individuals with OUD in rural areas, those without reliable transportation, and individuals with disabilities.

Although the DEA is charged with balancing the needs of ensuring access to controlled medications while limiting diversion, these restrictions all favor diversion control over medically indicated access. Diversion – that is, use of medications for OUD by someone other than the person to whom it was prescribed – is often raised as a justification for the limits imposed on OUD. However, research shows that "diverted" buprenorphine has the same positive health impacts as buprenorphine that was prescribed to the individual using it. Studies evaluating use of non-prescribed buprenorphine have demonstrated that it is primarily used for the purpose for which it was intended – helping people with OUD reduce use of other opioids and to treat symptoms of withdrawal (Chilcoat et al., 2019). Indeed, among adults with OUD, greater frequency of non-prescribed buprenorphine use is significantly associated with lower risk of overdose (Carlson et al., 2020). Improving access to treatment would likely reduce this concern by reducing the demand for non-prescribed buprenorphine.

Changes Made in Light of COVID-19

Several federal agencies have temporarily removed some barriers to the delivery of OAT during the COVID-19 pandemic. In the

methadone context, the Substance Abuse and Mental Health Services Administration (SAMHSA) issued guidance in late March that allows states to permit all patients who are on a stable methadone dose to receive 28 days of take-home medication, and for patients who are less stable to receive 14 days of take-home medication (SAMHSA, 2020). It is up to states to request this ability, however, and individual programs to implement the change.

Further, in consultation with SAMHSA, DEA has temporarily permitted OTPs to provide patients who are otherwise permitted to receive take-home doses of methadone to obtain those doses from temporary off-site locations, provided they are located in the same state in which the OTP is registered and meet certain other conditions. DEA also temporarily permits authorized OTP employees to personally deliver methadone to patients who cannot travel to the OTP to obtain the medication themselves and has authorized law enforcement and National Guard personnel to deliver methadone to patients as well. Due to other federal requirements, however, an individual must present in-person to an OTP to begin methadone treatment.

In the buprenorphine context, the HHS secretary, in coordination with the attorney general, have used existing statutory authority to waive the Ryan Haight Act's in-person examination requirement, thereby permitting the initial consultation for buprenorphine treatment to be held via telemedicine. While this authority was initially limited to communication conducted via an "audio-visual, real-time, two-way interactive communication system," DEA has recently used its enforcement discretion to authorize audio-only consultation as well (Prevoznik, 2020). This innovation is key, as it permits "tele-bupe" services whereby an individual with OUD can quickly and easily contact a waived provider who conducts a phone consultation and, where appropriate, prescribes buprenorphine and schedules appropriate follow-up.

Further, the HHS Office for Civil Rights, which enforces Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations, has issued a formal Notice that it will "exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency" and that "[a] covered health care provider that wants to use audio or video communication technology to provide telehealth to patients during the COVID-19 nationwide public health emergency can use any non-public-facing remote communication product that is available to communicate with patients" (HHS, 2020). While the Office notes that many audio-visual tools are HIPAA compliant, this use of enforcement discretion will permit providers to interact with patients who may not have access to professional software, including via programs that are regularly used on cell phones.

In acknowledgement of the fact that some prescribers may be responding to the crisis outside of the state in which they normally practice, DEA has waived, in some circumstances, the requirement that a DEA-registered provider obtain a separate DEA registration in each state in which they practice. In states that have granted reciprocity to providers licensed in other states during the public

health emergency, DEA will permit them to do so without obtaining a separate DEA registration for that state. The Agency explicitly notes that this waiver applies to the practice of telemedicine with patients located in states where the prescriber is not DEA-registered. Since DEA considers a provider to be practicing in the state in which their patient is located, this change may further improve the ability of providers to prescribe buprenorphine via telemedicine, particularly in rural areas and in smaller states.

Implementation of these changes has been uneven. Many states impose their own restrictions on methadone for OAT, and modifications to those restrictions are necessary to fully implement the modifications to federal law. For example, New York has implemented delivery of methadone to high-risk patients over 50 years old who are permitted at least seven days of take-home doses, and Oregon has issued guidance for OTPs that closely mirrors that from SAMHSA. Virginia's Medicaid program has provided guidance to OTPs that includes eliminating penalties for missed urine drug screens, and West Virginia has suspended counseling requirements for OTP patients during the COVID-19 emergency.

Federal flexibility regarding the use of telehealth seems to have been more widely implemented, likely due to the fact that telehealth for all fields of medicine has been expanded in the COVID-19 response. Many states have expanded their telehealth rules to include changes such as the approval of mental health providers' use of telehealth, payment parity with in-person visits, and authorized use of audio-only communication if necessary. However, some continue to impose limitations on this modality that exceed those in federal law (Augenstein et al., 2020).

Organizations in several states have begun offering buprenorphine hotlines, whereby individuals who want to begin buprenorphine treatment can connect with a waived provider over the phone. The provider then conducts an intake with the patient, prescribes buprenorphine if medically indicated, and schedules follow-up appointments. These programs can greatly reduce barriers to care for individuals who live in rural areas or who otherwise have difficulty accessing a waived provider. However, they are typically limited to individuals in certain geographical areas; there is no nationwide hotline to initiate buprenorphine treatment.

These modifications at the federal and state level likely will temporarily reduce the impact of the COVID-19 crisis on people with OUD and may help reduce some of the racial disparities exacerbated by both epidemics. However, all are in effect only during the COVID-19 emergency, and many require action on the part of states and other agencies to fully implement. Once the pandemic is resolved and the new coronavirus-related emergency declarations have expired, the older policies will resume. Such an outcome would be contrary to common sense and evidence-based practice and should not be permitted to occur. Both federal and state governments should make legislative and regulatory changes that permanently remove barriers to evidence-based OUD treatment. Congress should also act to remove barriers to OAT treatment, such as the requirement that providers who prescribe buprenorphine for OAT receive a "waiver" before doing so, that have not been waived during the COVID-19 outbreak. 🦠

Recommendations for Action

Federal government:

- Congress should:
 - o Amend 21 U.S.C. § 829(e) to permit clinicians to prescribe buprenorphine for OUD treatment without an initial in-person evaluation, including through audio-only interactions where necessary;
 - o Amend 21 U.S.C. § 823(g)(2) to permit all prescribers registered with the DEA to prescribe buprenorphine for OUD treatment without first obtaining a “waiver;”
 - o Amend 21 U.S.C. § 823(g)(2)(B)(iii) to remove or increase the cap on the number of patients a waived provider may treat with buprenorphine.
- The Secretary of Health and Human Services (HHS), should:
 - o In coordination with the Attorney General, use the statutory authority provided by 21 U.S.C. § 54(D) to waive the Ryan Haight Act’s in-person examination requirement for the duration of the federally declared opioid emergency;
 - o Remove restrictions on which patients may receive methadone for OUD by repealing 42 C.F.R. § 8.12(e);
 - o Repeal the requirement in 42 C.F.R. § 8.12(f)(2) that a prospective OTP patient undergo a “complete, fully documented physical evaluation” before admission;
 - o Repeal 42 C.F.R. § 8.12(h)(3)(ii) to remove initial dosing limitations on methadone treatment;
 - o Modify 42 C.F.R. § 8.12(i) to liberalize limitations on take-home methadone dosing;
 - o Modify 42 C.F.R. § 8.11(a)(1) to permit facilities such as pharmacies that do not meet all the requirements of 42 C.F.R. § 8.12 to dispense methadone for OUD treatment.

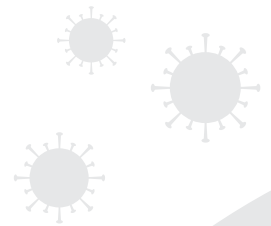
- The Attorney General should comply with the requirements of 21 U.S.C. § 831(h)(2) and promulgate regulations that permit all waived clinicians to prescribe buprenorphine without conducting an in-person examination of the prospective patient.
- Federal agencies that provide funding to graduate medical education, particularly the Centers for Medicare and Medicaid Services, should condition federal funding of residency programs on clinicians having received evidence-based instruction in OUD prevention, care, and treatment.

State governments:

- Legislators and regulatory agencies should:
 - o Remove restrictions on OTP siting and forbid localities from imposing same;
 - o Authorize the provision of buprenorphine via telehealth where applicable;
 - o Remove prior authorization and other payment barriers to OAT;
 - o Require state and local correctional facilities to screen for OUD and offer OAT as appropriate;
 - o Require all newly licensed physicians to obtain a waiver to prescribe buprenorphine for OAT.
- Legislators should reform criminal and child protection laws that serve as barriers to treatment access.
- Regulatory agencies should enable individuals with OAT to access a waived prescriber by calling a single, toll-free number.

Local governments:

- Local governments should
 - o Modify zoning and licensing laws that create barriers to the establishment of and access to methadone treatment facilities.
 - o Fully fund prevention and treatment initiatives.



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References

- Andrilla, C. H. A., Coulthard, C., & Larson, E. H. (2017). Changes in the Supply of Physicians with a DEA DATA Waiver to Prescribe Buprenorphine for Opioid Use Disorder. Retrieved July 13, 2020 from Rural Health Research & Policy Centers, http://depts.washington.edu/fammed/rhrc/wp-content/uploads/sites/4/2017/05/RHRC_DB162_Andrilla.pdf
- Augenstein, J., Marks, J. D., Morgan, V. E., & Peng, A. (2020). Executive Summary: Tracking Telehealth Changes State-by-State in Response to COVID-19. Retrieved July 27, 2020, from <https://www.manatt.com/insights/newsletters/covid-19-update/executive-summary-tracking-telehealth-changes-stat>
- Carlson, R. G., Daniulaityte, R., Silverstein, S. M., Nahhas, R. W., & Martins, S. S. (2020). Unintentional Drug Overdose: Is More Frequent Use of Non-Prescribed Buprenorphine Associated with Lower Risk of Overdose? *International Journal of Drug Policy*, 79(102722).
- Chilcoat, H. D., Amick, H. R., Sherwood, M. R., & Dunn, K. E. (2019). Buprenorphine in the United States: Motives for Abuse, Misuse, and Diversion. *Journal of Substance Abuse Treatment*, 104, 148-157.
- Davis, C. S., & Carr, D. H. (2017). The Law and Policy of Opioids for Pain Management, Addiction Treatment, and Overdose Reversal. *Indiana Health Law Review*, 14(1), 1-39.
- Davis, C. S., & Carr, D. H. (2019). Legal and Policy Changes Urgently Needed to Increase Access to Opioid Agonist Therapy in the United States. *International Journal of Drug Policy*, 73, 42-48.
- Lagisetty, P. A., Ross, R., Bohnert, A., Clay, M., & Maust, D. T. (2019). Buprenorphine Treatment Divide by Race/Ethnicity and Payment. *JAMA Psychiatry*, 76(9), 979-981.
- Leshner, A. I., & Dzau, V. J. (2019). Medication-Based Treatment to Address Opioid Use Disorder. *Journal of the American Medical Association*, 321(21), 2071-2072.
- Prevoznik, T. (2020). Letter from Thomas W. Prevoznik, Deputy Assistant Administrator, Diversion Control Division, U.S. Department of Justice, to DEA Qualifying Practitioners and DEA Qualifying Other Practitioners. DEA068. March 31, 2020. Retrieved July 13, 2020 from [https://www.deadiversion.usdoj.gov/GDP/\(DEA-DC-022\)\(DEA068\)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20\(Final\)%20+Esign.pdf](https://www.deadiversion.usdoj.gov/GDP/(DEA-DC-022)(DEA068)%20DEA%20SAMHSA%20buprenorphine%20telemedicine%20(Final)%20+Esign.pdf)
- Rouben R. (2018). HHS Chief Pitches New Measures to Expand Opioid Addiction Treatment. *The Hill*. Retrieved July 13, 2020, from <http://thehill.com/policy/healthcare/375455-hhs-chief-pitches-new-measures-to-expand-opioid-addiction-treatment>
- Sordo, L., Barrio, G., Bravo, M. J., Indave, B. I., Degenhardt, L., Wiessing, L., Ferri, M., & Pastor-Barriuso, R. (2017). Mortality Risk During and After Opioid Substitution Treatment: Systematic Review and Meta-analysis of Cohort Studies. *British Medical Journal*, 357, j1550.
- Substance Abuse and Mental Health Services Administration (SAMHSA)(2020). Opioid Treatment Program (OTP) Guidance. Retrieved July 27, 2020, from <https://www.samhsa.gov/sites/default/files/otp-guidance-20200316.pdf>
- U.S. Department of Health and Human Services (HHS)(2020). Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID-19 Nationwide Public Health Emergency. Retrieved July 13, 2020, from <https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html>
- Controlled Substances Dispensed by Means of the Internet, 21 U.S.C. § 829(e)(2020).
- Wilson, N., Kariisa, M., Seth, P., Smith, H. IV, & Davis, N. L. (2020). Drug and Opioid-Involved Overdose Deaths - United States, 2017-2018. *Morbidity and Mortality Weekly Report*, 69(11), 290-297.

Legal Strategies for Promoting Mental Health and Wellbeing in the COVID-19 Pandemic

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SUMMARY. While mental health is often viewed as a matter of individual treatment of mental illness, mental health and well-being may be promoted throughout the population, including through law and policy. The inadequacy of our mental health care system, including limited public and private insurance coverage and provider shortages, has been apparent during the response to COVID-19, though expanded access to tele-mental health has closed the gap somewhat. Inability to meet basic needs contributes to stress, anxiety, and depression, so COVID-19 response measures to ensure access to employment or unemployment benefits, housing, food, childcare, and the like are critical to community mental health. Interventions aimed at mental health, such as Psychological First Aid, the Crisis Counseling Program, suicide prevention, and violence prevention programs can promote feelings of calm and safety, while supporting collaboration, nurturing problem-solving skills, and increasing hope. Long-standing inequities have contributed to higher infection and mortality rates, especially among African-Americans, Latinos, and Native Americans, while Asian-Americans have been targeted with harassment and discrimination, making legal action to support mental health in communities of color essential. With schools abruptly shifting to remote learning in spring, school-based mental health services and opportunities for social emotional learning were disrupted. Intentional support for the mental health and wellbeing of students, teachers, school employees, and parents is needed this fall, regardless of educational setting. If the COVID-19 pandemic is viewed as a mass trauma, strategies to support posttraumatic growth ought to be at the forefront of pandemic response, recovery, and restructuring.

Introduction

Mental health has not been a major focus of emergency preparedness, despite the fact that mental health harms are frequently among the most severe and long-lasting harms caused by natural disasters and disease outbreaks. The COVID-19 pandemic may be viewed as a mass trauma experienced throughout the world, including throughout the United States. Uncertainty, loss of life, severe illness, lack of personal protective equipment, economic upheaval, structural racism, limitations on daily activities, and isolation have taken a substantial toll. By July, over 50% of respondents to a Kaiser Family Foundation Health Tracking Poll indicated that worry or stress about the new coronavirus had negatively affected their mental health (Hamel et al., 2020). While mental health is often seen through a lens of individual treatment of mental illness, mental health may also be promoted throughout the population, including through law and policy.

The COVID-19 pandemic and ensuing public health measures intended to prevent the spread of the new coronavirus have introduced disruption on a greater scale than many people have seen in their lifetimes. The field of positive psychology posits a “dual continuum” model, in which mental illness may be shown on the x-axis (one either is or is not mentally ill), and mental health may be shown on the y-axis (one is either flourishing or languishing). According to the research, people who describe themselves as flourishing typically engage in six core activities nearly every day: interacting, helping others, playing, moving (physical activity), spiritual activity, and learning something new (Catalino & Fredrickson, 2011). It is jarring to review this list in the context of the closure of most workplaces, schools, faith communities, gyms, restaurants, etc., and realize how precisely COVID-19, physical distancing, and community mitigation combine to threaten the core pillars of wellbeing. Of course, many individuals and communities found ways to interact and continue to learn new things online.

Where concern about COVID-19 was initially described as a fear of infection and a rise in anxiety in response to uncertainty about the disease itself, a more nuanced portrait has emerged. A team of researchers coined the term COVID Stress Syndrome, which includes fear of COVID-19, socioeconomic concerns, traumatic stress symptoms, xenophobia, and compulsive checking and reassurance seeking (Taylor et al., 2020). As Taylor et al. observed: “Our findings suggest that the psychological footprint of COVID-19 is likely to be more substantial than the medical footprint. That is, at the time of conducting this study the number of people emotionally affected by COVID-19 far exceeded the number of people who had been infected.” Some of those affected were severely affected, while many were able to employ coping mechanisms, whether adaptive or maladaptive to help them get through the period of self-isolation. The researchers noted that few people in their study reported seeking medical or mental health treatment to support their coping.

The Law of Mental Health and Wellbeing During the COVID-19 Pandemic

In general, emergency preparedness laws are nearly silent with respect to mental health treatment and promotion. For example, the Pandemic and All Hazards Preparedness and Advancing Innovation Act of 2019 only touches on mental health in a few provisions related to the role of the assistant secretary for mental health and substance abuse, consultation with mental health facilities during emergency preparedness planning, and inclusion of an expert in pediatric mental health in the membership of a national advisory committee on children and disaster. Notably, the Act authorizes the hospital preparedness program, which provides funds and technical assistance for healthcare coalitions, whose efforts to encourage a resilient healthcare workforce may include training in psychological first aid. Additional funding for hospital preparedness was provided in the Coronavirus Aid, Relief, and Economic Security (CARES) Act. Its predecessor, the Pandemic and All Hazards Preparedness Act of 2006, provided funding for Preparedness and Emergency Response Learning Centers, university-based centers that developed and disseminated trainings on psychological first aid, but this funding was not continued.

Substantial federal authority was invoked when the president declared a nationwide emergency under the Stafford Act on March 13, and when he approved major disaster declarations for all 50 states, the District of Columbia, and four territories. Numerous Tribes are collaborating with the federal government under the emergency declaration. The Crisis Counseling Program is authorized under a major disaster declaration, but not an emergency declaration, including a public health emergency declaration. The Crisis Counseling Program provides federal funding and technical assistance to states, so that they may provide crisis counseling.

The Mental Health Parity and Addiction Equity Act of 2008 and the Affordable Care Act provide that to the extent private health insurers provide insurance coverage for physical health concerns, their coverage for mental health concerns must be comparable.

However, these laws have not yet resulted in parity in coverage for mental health treatment.

A number of laws address mental health promotion among children and adolescents. The maternal, infant, and early childhood home visiting programs support education and coaching in parenting skills among new parents, promoting greater connection with their very young children, reducing stress, and preventing adverse childhood experiences. The federal Every Student Succeeds Act provides authority for grants to state and local education agencies to create the conditions for student learning and improve the school climate. State laws and benchmarks may advance social and emotional learning. These educational approaches can be implemented online, too (CASEL, 2020). Other state laws may promote school mental health in the context of the COVID-19 pandemic—these laws include a law requiring instruction in mental health first aid for teachers in Florida; a law requiring that mental health be addressed in health education courses, in New York and Virginia; and an Oregon law recognizing student absences from school in order to protect and care for their mental health, just as they may have absences in order to care for their physical health.

Finally, most people will navigate the pandemic, but some will not. Suicide rates, which were at historic highs prior to the COVID-19 pandemic, may increase substantially, particularly if unemployment benefits and eviction moratoria are permitted to lapse (Pettersson et al., 2020). Evidence-based laws that decrease the risk of suicide include the Garrett Lee Smith Act, which provides for grants from the federal government to state and Tribal governments. In addition, red flag laws that limit the access to guns of people found to be a danger to themselves or others have been effective in preventing deaths by suicide in states as politically and culturally diverse as Indiana and Connecticut.

Assessment

The literature and scientific opinion have coalesced around five key principles in response to mass trauma:

- Promote Sense of Safety
- Promote Calming
- Promote Sense of Self- and Collective Efficacy
- Promote Connectedness
- Promote Hope

(Hobfoll et al., 2007). These principles provide valuable guidance for assessing and strengthening the legal response to the COVID-19 pandemic.

Federal legislation enacted in response to the COVID-19 pandemic sought to address many of the practical conditions that might otherwise have contributed to even poorer mental health (Purtle et al., 2020). This assistance is discussed in other chapters of this Report and includes unemployment benefits; moratoria on evictions; SNAP and a modified National School Lunch Program; sick leave for those remaining at home while ill with the new

coronavirus; and paid family leave for those caring for those ill with the new coronavirus or home from school. Because many of these legal interventions are time-limited, however, recipients may experience anxiety and uncertainty about when and whether these social supports may disappear. Congress should promptly act to extend these vital interventions in order to maintain a sense of safety; a lapse in these supports will make it more difficult to restore a sense of safety.

The lack of enforcement of mental health parity laws, and the lack of focus on mental health in emergency preparedness laws, made the response less effective. For those seeking individual mental health treatment, however, administrative changes by the Centers for Medicare and Medicaid Services and the Office of Civil Rights within the Department of Health and Human Services expanded access to telehealth, including tele-mental health, by adjusting eligibility for reimbursement for telehealth and by suspending requirements related to privacy and security of platforms for telehealth. The rapid steps taken to expand access to telehealth appear to have been largely successful, though the extent to which people are taking advantage of these services for mental health care is unclear. Joining the Psychology Interjurisdictional Compact may be one means for states to support expanded access to tele-mental health following the pandemic.

The unprecedented issuance of a major disaster declaration for a public health emergency, and subsequent availability of the Crisis Counseling Program, was a bold step and commensurate with the scope and nature of the need. However, crisis counseling services have not been funded at adequate levels or promoted and advertised consistently in the states, and an April 28 presidential memo approving the Crisis Counseling Program ordered funds to be allocated in unnecessarily complex ways. Moreover, the Crisis Counseling Program is limited to a period of nine months following a disaster, which presupposes a single, finite disaster event, not an ongoing pandemic. Crisis counseling is often explicitly focused on enhancing self-efficacy through providing support with problem-solving and coping skills. In order to be better prepared for a future pandemic, Congress should amend the Stafford Act to authorize the Crisis Counseling Assistance and Training Program under public health emergencies when appropriate, and remove the limitation of assistance to nine months following the disaster.

Prior investments in emergency preparedness research had resulted in online curriculum and trainings in Psychological First Aid, and even policy adoption (Birkhead & Vermeulen, 2018). Renewed investment in research and training is needed, including investment in culturally competent approaches and trainers. Healthcare preparedness coalitions should be invited to provide feedback on whether psychological first aid training strengthened their emergency preparedness and response, and how these efforts could be improved (Birkhead & Vermeulen, 2018).

Though the CARES Act authorized an additional \$50 million for suicide prevention, the legislation enacted to date has not centered mental health as a priority. Future legislation should prioritize mental health promotion, commensurate with the detrimental impact of COVID-19 on mental health. The legislation should address mental health literacy and stigma reduction;

structural racism and the social determinants of health; public safety, including suicide and injury prevention; and access to care and treatment. In order to inspire hope, as it begins to focus on a longer-term vision for recovery, Congress should search for models that support posttraumatic growth among populations, such as interventions with veterans. As the experience of elderly residents of nursing homes demonstrates, promoting social connections to combat loneliness should be as much a priority as infectious disease control measures.

State and local governments provided messaging and enforcement regarding discrimination against Asian-Americans, and other individuals based upon race, ethnicity, and national origin, with some local governments such as New York City establishing task forces to address discrimination and COVID-19. These efforts must continue and expand. Left unchecked, racial discrimination, harassment, and bullying have a corrosive effect on mental health.

Limited data collection by race and ethnicity in most jurisdictions in the early stages of the pandemic impeded a proactive response to racial disparities. Milwaukee was one of the first jurisdictions to adopt a statement naming racism as a public health crisis in 2019, and it is no coincidence that it was one of the first cities to note racial disparities in infection and mortality rates. Higher infection and mortality rates reflect disproportionate representation in low-wage jobs at high risk for COVID-19, as well as higher rates of chronic disease such as diabetes, asthma, and cardiovascular disease. They have resulted in a greater weight of grief for many people of color who have lost multiple loved ones, and increased anxiety for those worried about the high levels of risk to themselves and their communities. These effects were compounded by highly publicized police killings of Black Americans, including George Floyd and Breonna Taylor. Repeated exposure to police violence directed toward Black people on social media have harmful mental health impacts upon Black people. Black Americans may possess unique protective factors, including social support and culturally specific coping skills (Novacek, 2020). Evidence-based legal strategies to address structural racism and strengthen protective factors are needed to increase health equity.

Schools scrambled to transition to remote learning and most were not focused upon mental health in the early months of the pandemic. Whether or not students return to in-person school in the fall, the mental health of all persons within school, university, and community college systems—from teachers and school employees, to students, to parents – warrants sustained legal and policy attention. Investments in home visiting programs, parenting skills programs, and universal pre-kindergarten are all strategies that can reduce adverse childhood experiences, nurture coping skills, and promote emotional wellbeing. A growing body of evidence supports the importance of access to nature for mental health, such that outdoor learning initiatives may support physical distancing, reduce stress, and increase equity. Implementing continuing education requirements regarding mental health and suicide prevention for health care providers may provide an early warning system for individuals and the population as a whole. Health departments may wish to become trauma informed systems in order to more effectively respond to the mental health impacts of COVID-19. 🌱

Recommendations for Action

Federal government:

- Extend investment in measures to address the economic disruptions associated with COVID-19 and the public health response, including employment (Paycheck Protection Program) and unemployment benefits, SNAP and modified National School Lunch Program, eviction moratoria, and paid sick leave and family medical leave for those ill with COVID and those caring for those ill with COVID-19.
- Amend the Stafford Act to authorize the Crisis Counseling Assistance and Training Program under public health emergencies when appropriate, and remove the limitation of assistance to nine months following the disaster.
- Provide greatly increased financial support, technical assistance, and marketing for the Crisis Counseling Program in every state.
- Renew and increase investment in research and culturally competent training in Psychological First Aid.
- Require regular training in Psychological First Aid as a condition of receipt of emergency preparedness funds, such as Healthcare Preparedness Coalitions.
- Increase investment in maternal, infant, and early childhood home visiting programs, and provide technical assistance and guidance to prevent the spread of COVID-19.
- Increase investment in suicide prevention programs funded through the Garrett Lee Smith Act.
- Extend regulatory flexibility related to reimbursement, privacy and security, and licensure portability for tele-mental health beyond the response to this pandemic.
- Extend regulatory flexibility related to reimbursement, privacy and security, and licensure portability for tele-mental health.
- Consider joining the Psychology Interjurisdictional Compact.
- Increase investment in maternal infant and early childhood home visiting programs, and provide technical assistance and guidance to support physical distancing and other measures to prevent the spread of COVID-19.
- Make free, public pre-kindergarten available to all children in the state, and establish guidelines regarding social and emotional learning.
- Support education about mental health in K-12 schools, including providing Mental Health First Aid training for teachers and addressing mental health as an aspect of health in K-12 health education courses. Adapt requirements for remote learning environments.
- Provide education and practice in social and emotional learning skills for all adults involved in school settings, including online learning, and integrate social and emotional learning and skills practice in preschool-12 instruction.
- Fund mental health education and services in public universities and community colleges.
- Incorporate information and skills related to mental health assessment and suicide prevention in continuing education requirements for health care providers.
- Expand funding and efforts toward trauma informed care and suicide prevention, including targeted efforts to support African American, Native American, and LGBTQ youth, and other groups at heightened risk
- Enact and implement laws to limit access to guns among those who are shown to pose a danger to themselves or others (extreme risk protection orders or red flag laws).
- Actively enforce anti-discrimination laws and provide proactive education regarding their requirements.
- Increase the minimum wage.
- Identify and fund gaps in practical assistance at the federal level, such as diaper need, which may be addressed through grants and assistance to diaper banks, assistance to families receiving work support, and exemptions from state sales tax.

Local governments:

- Health departments should consider integrating trauma-informed approaches in all of their work and programming and becoming trauma informed systems (San Francisco Department of Public Health).
- Provide periodic training in psychological first aid, as well as evidence-based stress management and mindfulness training, to all employees. Adapt training to online modalities.
- Review Employee Assistance Programs for adequacy to meet increased need among government employees, including first responders, as a result of COVID-19.
- Increase capacity of teachers and first responders to identify and refer persons experiencing mental health challenges through mental health first aid and crisis intervention training.
- Provide education and practice in social and emotional learning skills for all adults involved in school settings, including remote learning, and integrate social and emotional learning and skills practice in preschool-12 instruction.
- Actively enforce anti-discrimination laws and provide proactive education regarding its requirements.
- Consider whether declaring racism to be a public health crisis in the jurisdiction could focus efforts to address racial disparities and increase health equity.

State governments:

- Adopt and enforce mental health parity requirements that are at least as strong as federal requirements.

Local government recommendations, continued:

- Implement measures to ensure equitable access to nature and green space, including through temporary road closures, use of public golf courses, and outdoor learning initiatives.
- Consider initiatives to increase social connection and reduce loneliness, including among senior citizens.

About the Author

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References

- Birkhead, G. S., & Vermeulen, K. (2018). Sustainability of Psychological First Aid Training for the Disaster Response Workforce. *American Journal of Public Health*, 108(S5), S381-S382.
- Brooks, S. K., Webster, R. K., Smith, L. E., Woodland, L., Wessely, S., Greenberg, N., & Rubin, G. J. (2020). The Psychological Impact of Quarantine and How To Reduce It: Rapid Review of the Evidence. *The Lancet*, 395, 912-920.
- Catalino, L. I., & Fredrickson, B. L. (2011). A Tuesday in the Life of a Flourisher: The Role of Positive Emotional Reactivity in Optimal Mental Health. *Emotion*, 11(4), 938-950.
- Collaborative for Academic, Social and Emotional Learning (CASEL)(2020). *An Initial Guide to Leveraging the Power of Social and Emotional Learning: As You Prepare to Reopen and Renew Your School Community*. Retrieved July 20, 2020, from https://casel.org/wp-content/uploads/2020/05/CASEL_Leveraging-SEL-as-You-Prepare-to-Reopen-and-Renew.pdf
- Hamel, L., Kearney, A., Kirzinger, A., Lopes, L., Munana, C., & Brodie, M. (2020). Coronavirus: Schools, Reopening, and the Government Response. Retrieved July 29, 2020 from Kaiser Family Foundation, <https://www.kff.org/coronavirus-covid-19/report/kff-health-tracking-poll-july-2020/>
- Hobfoll, S. E., Watson, P., Bell, C. C., Bryant, R. A., Brymer, M. J., Friedman, M. J., Friedman, M., Gersons, B. P. R., de Jong, J. T. V. M., Layne, C. M., Maguen, S., Neria, Y., Norwood, A. E., Pynoos, R. S., Reissman, D., Ruzek, J. I., Shalev, A. Y., Solomon, Z., Steinberg, A. M., & Ursano, R. J. (2007). Five Essential Elements of Immediate and Mid-Term Mass Trauma Intervention: Empirical Evidence. *Psychiatry: Interpersonal and Biological Processes*, 70(4), 283-315.
- Novacek, D. M., Hampton-Anderson, J. N., Ebor, M. T., Loeb, T. B., & Wyatt, G. (2020). Mental Health Ramifications of the COVID-19 Pandemic for Black Americans: Clinical and Research Recommendations. *Psychological Trauma: Theory, Research, Practice, and Policy* (forthcoming).
- Petterson, S., Westfall, J. M., & Miller, B. F. (2020). Projected Deaths of Despair from COVID-19. Retrieved July 20, 2020 from Well Being Trust, https://wellbeingtrust.org/wp-content/uploads/2020/05/WBT_Deaths-of-Despair_COVID-19-FINAL-FINAL.pdf
- Purtle, J., Nelson, K. L., Counts, N. Z., & Yudell, M. (2020). Population-Based Approaches to Mental Health: History, Strategies, and Evidence. *Annual Review of Public Health*, 41, 201-221.
- Schechter, A., Diaz, F., Moise, N., Anstey, D. E., Ye, S., Agarwal, S., Birk, J. L., Brodie, D., Cannone, D. E., Chang, B., Claassen, J., Cornelius, T., Derby, L., Dong, M., Givens, R. C., Hochman, B., Homma, S., Kronish, I. M., Lee, S. A. J., Manzano, W., Mayer, L. E. S., McMurry, C. L., Moitra, V., Pham, P., Rabbani, L., Rivera, R. R., Schwartz, A., Schwartz, J. E., Shapiro, P. A., Shaw, K., Sullivan, A. M., Vose, C., Wasson, L., Edmondson, D., & Abdalla, M. (2020). Psychological Distress, Coping Behaviors, and Preferences for Support Among New York Healthcare Workers During the COVID-19 Pandemic. *General Hospital Psychiatry*, 66, 1-8.
- Taylor, S., Landry, C. A., Paluszek, M. M., Fergus, T. A., McKay, D., & Asmundson, G. J. G. (2020). COVID Stress Syndrome: Concept, Structure, and Correlates. *Depression and Anxiety* (forthcoming).

Implementation and Enforcement of Quality and Safety in Long-Term Care

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SUMMARY. Long before the new coronavirus struck, nursing homes and other long-term care facilities have had declining quality care that coincides with inadequate staffing and rampant infections. These pre-pandemic conditions increased the vulnerability of these facilities to an infectious disease outbreak. As the elderly death toll rises into the tens of thousands, an overdue national discussion on how to prioritize long-term care in the US has emerged, revealing an opportunity to better link quality care metrics with sufficient reimbursement and meaningful regulatory oversight. However, the opposite approach has also surfaced, which would allow the status quo to continue and may erode the minimum standards of care that currently exist. This concerning trend is on the rise with efforts to relax the Centers for Medicare and Medicaid Services (CMS) regulatory authority over nursing homes by waiving requirements and reducing enforcement penalties. In addition, states are passing measures to limit liability exposure for nursing homes during COVID-19 and similar protections are under consideration at the federal level, even as infection rates climb and there is no evidence of frivolous lawsuits. While political will is uncertain, public outcry is ready for legislative reform that will lead to better later-in-life care. The stakes have never been higher – act now and pass laws that connect funding with regulation to support quality care in nursing homes during and after the COVID-19 pandemic – or continue to condone practices that allow infection to spread and take many lives before their time.

Introduction

Across the country, nursing homes and long-term care facilities struggle with how to contain the coronavirus outbreak. Part of the difficulty relates to conflict between federal, state, and nursing homes that emerged as thousands of COVID-19 infections and related deaths became linked to these facilities. This Chapter identifies and reviews the major missteps in response to COVID-19 that were facilitated by laws and regulations (or lack thereof) and provides recommendations for how to better control an infectious disease outbreak through improving quality care in long-term care.

Major Missteps

The following three areas: staffing, infectious disease controls and prevention, and emergency planning and accountability, require strengthened legislation and regulatory oversight to curb the spread of COVID-19.

Staffing. Pre-pandemic staffing levels fell far short of what is recommended (Harrington et al., 2020). Previous proposals to mandate minimum staffing levels have failed across the states

largely due to the nursing home industry citing cost concerns. This staffing shortage led to undue pressure for workers to continue working in potentially dangerous conditions, and low wages have made it difficult for workers to earn sufficient income without working at multiple facilities. Specifically, recent evidence finds certified nursing aides (CNAs) have unwittingly passed on the virus, as an estimated 15% to 17% work at more than one long-term facility and are commonly referred to as 'superspreaders' (Harold Van Houtven et al., 2020).

CNAs are primarily immigrants and women of color who earn low-wages, and report fear of reprisal for requesting paid sick leave and PPE. These workers represent systemic racial, gender, and economic inequalities in nursing home care that has long been relegated to the shadows, despite their essential role in caring for older Americans. In the midst of COVID-19, some states support wage increases or hazard pay to encourage CNAs to work at only one facility. Adequate PPE and paid sick leave laws with enforcement could further reduce the spread of COVID-19, along with some of the inequities facing this vulnerable population.

CNAs and other nursing home staff across the country have filed hundreds of COVID-19 related complaints with the Occupational Safety and Health Administration (OSHA) claiming their employers are putting them in danger of being exposed to the coronavirus. Workers' fears are palpable in these complaints in which they report being forced to work while symptomatic or even if tested positive for COVID-19, lacking PPE, and being kept in the dark about outbreaks in their own facilities. OSHA, the agency charged with enforcing workplace safety law, has dismissed the vast majority of the complaints received and has yet to promulgate legally binding regulations to enforce employer compliance.

Infectious Disease Controls and Prevention. Similar to staff shortages, rampant infections are also a pre-pandemic problem. Tens of thousands of nursing home residents annually die from infections, which commonly include urinary tract infections, diarrheal diseases, and staph infections. A Government Accountability Office report released in 2019 analyzed CMS data and found that 82% of nursing homes, over 13,000 facilities, had received citations related to poor infection control (GAO-19-433, 2019). These findings highlight how pre-pandemic conditions contributed to the spread of COVID-19 in facilities charged with caring for older adults.

The ease with which COVID-19 is transmitted makes containment more challenging, which calls for greater infection control and prevention measures. Long-term care facilities, similar to other congregate settings such as cruise ships, prisons, and shelters, group large numbers of people together for communal meals and other services. In addition, personal care needs of an older population add a layer of necessary physical contact as residents often need assistance with bathing, dressing, and toileting, further limiting the feasibility of recommended safety measures such as social distancing. CMS and the Centers for Disease Control and Prevention (CDC) saw this as an issue concerning enough to generate specific guidance for long-term care facilities (CMS, 2020). This guidance issued on April 2, 2020 outlines necessary protocols, including isolating residents with symptoms, promptly reporting cases, and implementing emergency planning. Despite this awareness, many facilities failed to implement basic health and safety protocols.

Relatedly, facilities receiving CMS funding must comply with Conditions of Participation, which establish standards for quality of care metrics, staffing, and other services, which CMS monitors and rates on a five-star system (42 C.F.R. § 483.1, 2020). In theory, such monitoring should lead to data-driven regulation, where poorly performing facilities could be identified and improved. For example, one might assume that Life Care Center of Kirkland, Washington, known for its systematic failure in response to COVID-19, would have a low CMS rating. Yet, this facility received a five-star rating right before the pandemic. A recent study found the CMS rating system was not a predictor for the COVID-19 infection outbreaks, suggesting current data collection and reporting methods should be revisited (Gebeloff et al., 2020).

Despite its potential flaws, the CMS data has been useful in showing widespread deficiencies in quality care at nursing homes. In spite

of this evidence, there are efforts to relax CMS requirements and enforcement, as well as calls to protect nursing homes from liability. For example, under the Trump administration, nursing homes are given a one-time fine for most violations rather than a fine for each day there is a deficiency, reducing average fines by one-third. Furthermore, CMS is proposing a rule to remove requirements under the Conditions of Participation deemed "obsolete or excessively burdensome," which shockingly, includes the requirement for facilities to employ an infection prevention specialist (84 Fed. Reg. 34737, 2019).

Many states have passed executive orders or legislation limiting nursing home liability exposure during COVID-19. The long-term care industry is now proposing Congress pass national immunity from liability. The rise in infections and declining role of regulatory oversight make this potential immunity all the more concerning for ensuring minimum standards of care (Sklar & Terry, 2020).

Emergency Planning and Accountability. Conflicting guidance from federal and state authorities has been a recurring theme during this pandemic, reflecting an overall poor approach to emergency planning. For example, many governors issued executive orders to transfer recovering COVID-19 patients to nursing homes in order to free up intensive care unit beds. However, some nursing homes lacked sufficient PPE, testing kits, adequate staffing, and ability to isolate residents, which likely contributed to the outbreaks these facilities experienced after admitting the recovering patients. Governor Cuomo issued this controversial order in New York on March 25, then reversed it on May 10, claiming the nursing homes should not have admitted these patients if they couldn't have isolated them. However, this runs counter to the orders which state, "no resident shall be denied re-admission or admission to the [nursing home] solely based on confirmed or suspected COVID-19" (Graham, 2020). If a resident was not critically ill, it was unclear how a nursing home could deny admissions, leaving staff and residents in the crosshairs of accepting COVID-19 positive residents without the resources to prevent an outbreak.

Lastly, the distribution of federal COVID-19 funding to nursing homes fails to directly address deficiencies contributing to the spread of the coronavirus. On May 22, 2020, HHS announced a \$4.9 billion nursing home allocation, with \$50,000 per facility, plus \$2,500 per bed (HHS Press Release, 2020). This funding does not earmark PPE, testing capacity, staffing, or other infection control measures, rather funds can be broadly used "to offset significant expenses or lost revenue attributable to the COVID-19."

Assessment

This section assesses the aforementioned missteps and proposes legislative and regulatory action.

Stronger Oversight and Tougher Enforcement

Regulatory action alone is not enough to mitigate the threat of COVID-19 in nursing homes. There are federal and state obligations already in place that need to be legally enforced for optimal effectiveness. During the pandemic, some states have addressed

staffing shortages and improved infection control through governor executive orders and legislation, saving lives in the process. These approaches highlight what could be possible were funding tied to quality metrics with effective enforcement.

The majority of states have improved facility staffing shortages and addressed other essential needs by deploying the National Guard. Maryland was one of the first states to send in the National Guard to join emergency strike teams for nursing homes, which provide emergency care, supplies, and equipment. Other states called in the Guard for disinfecting (Georgia), testing (Florida), boosting staffing levels (California), performing inspections (Connecticut), and contract tracing (Washington). Currently, the Guard deployment ends in mid-August, which could have devastating consequences if the pandemic is not under control and these services are stopped.

Workplace safety has failed on many fronts throughout the pandemic, largely due to OSHA and its state agencies' failure to execute legally binding regulations. There are current federal regulations to protect employees from hazardous conditions under the General Duty Clause, which during this pandemic could authorize the use of PPE. Under this clause, OSHA could issue a directive requiring employers to comply with CDC guidelines for PPE and other safety measures, but they have yet to do so. OSHA's enforcement is minimal, with only a handful of onsite inspections occurring in response to the hundreds of complaints from CNAs, nursing home and long-term care staff. Relatedly, wage increase or hazard pay and paid sick leave with retaliation protection could support CNAs, whom are largely immigrants and women of color, decision to work at one facility and stay home if symptomatic for a possible COVID-19 infection.

Lastly, granting nursing homes immunity from lawsuits related to COVID-19 is a concerning trend emerging across the states and proposed at the federal level. A central argument of industry groups requesting immunity is the national shortage around PPE and testing kits that limits their ability to control the spread of COVID-19 in facilities. While there are valid concerns regarding the unprecedented nature of COVID-19, these concerns do not justify granting immunity to an industry with a history of misconduct that has failed to implement basic health and safety procedures.

Transparency and Data

The lack of timely, accurate, and reliable data about COVID-19 cases in nursing homes has hampered attempts to control the spread of infection. After pressure from the media, public, lawmakers, and resident advocacy groups, CMS released an interim final rule requiring nursing homes to submit weekly updates to CMS and CDC about confirmed and suspected COVID-19 infections and deaths at their facilities (85 Fed. Reg. 27550, 2020). The first report was due on May 8, 2020, and while the time lag is another notable misstep, this data should be useful for regulators to better track, respond to, and mitigate the spread of COVID-19. The rule also includes updates on requirements for PPE supplies, access to COVID-19 testing, and staffing shortages.

The CMS five-star rating system has not consistently identified which facilities are at higher risk for spread of infection. Perhaps with the integration of this additional weekly data, the CMS rating system can be improved. Currently, there is no published data on the race of nursing home residents by facility. As COVID-19 disproportionately impacts minorities, collecting these data points could inform a more effective response.

Additionally, more comprehensive data could lead to more targeted federal and state funding efforts. For example, the \$4.9 billion distribution of funds by HHS to nursing homes based on the number of beds could include variables such as PPE and staffing shortages, substantial violations, and staff complaints, in order to identify and optimally support high-risk facilities. Promising federal legislation does just this, linking federal funding with quality care metrics. The Quality Care for Nursing Home Residents and Workers During Covid-19 Act was introduced on May 5, 2020, in the U.S. House of Representatives (H.R. 6698, 2020). This bill proposes to increase regulatory inspections with stricter protocols around testing and reporting tied to distribution of funds for improving the level of care, rather than a general bed count. Ultimately, more funding alone will not help Americans through this process; the dollars must be linked to timely and accurate data in order to address the root causes of how the coronavirus is spreading.

There are many lessons to be learned from the response to COVID-19 in nursing homes and long-term care facilities. Regulatory action and legislation could save lives now and improve quality care for older American in the years ahead. Other efforts to further relax regulations, enforcement, and allow immunity from lawsuits could further erode a system already renowned for poor care. It is frightening to imagine a future where after this horrific event, the legislation that passes only serves to put older Americans and the general public in further harm's way should another pandemic strike. 🦠

Recommendations for Action

Federal government:

- CMS should mandate adequate staffing ratios in nursing homes and long-term care facilities.
- The administration should extend the National Guard deployment, continuing to fund Guard assistance to nursing homes and their residents.
- OSHA should pass legally binding regulations that makes employer compliance with PPE and other CDC safety measures compulsory under the General Duty clause.
- Congress should significantly expand OSHA's enforcement resources for effective follow-up on complaints from nursing home and long-term care staff.
- CMS should withdraw its proposed rule entitled, Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency and Transparency.
- Congress should not pass a federal law granting nursing homes immunity from liability during COVID-19.
- CMS should expand the nursing home dataset to include racial demographics of residents.
- Congress should include the proposed Quality Care for Nursing Home Residents and Workers During COVID-19 Act of 2020 in the next coronavirus relief package or similar legislation that links regulatory oversight with funding to improve quality care and health outcomes.

State governments:

- Nursing home regulators should mandate adequate staffing ratios in nursing homes and long-term care facilities.
- Legislators should support wage increases or hazard pay for CNAs to encourage them to only work at a single facility.
- State administrations should amend or reverse any executive orders that require nursing homes to take COVID-19 positive patients if they do not have the PPE supplies and ability to adequately isolate them.
- State governors or legislators should not grant nursing homes immunity from liability during COVID-19.
- Legislators should significantly expand state OSH agency enforcement resources.

Local governments:

- Local governments should enact paid sick leave requirements with retaliation protection.



About the Author

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References

Conditions of Participation, 42 C.F.R. § 483.1 (2020).

GAO-19-433 (2019). Nursing Homes: Improved Oversight Needed to Better Protect Residents from Abuse.

Centers for Medicare and Medicaid (2020). COVID-19 Long-Term Care Facility Guidance. Retrieved July 19, 2020, from <https://www.cms.gov/files/document/4220-covid-19-long-term-care-facility-guidance.pdf>

Gebeloff, R., Ivory, D., Richtel, M., Smith, M., Yourish, K., Dance, S., Fortier, J., Yu, E., & Parker, M. (2020). The Striking Racial Divide in How Covid-19 has Hit Nursing Homes. Retrieved June 12, 2020, from <https://www.nytimes.com/article/coronavirus-nursing-homes-racial-disparity.html?smid=tw-share>

Graham, J. (2020). Coronavirus Patients Caught in Conflict Between Hospital and Nursing Homes. Retrieved June 12, 2020, from <https://khn.org/news/coronavirus-patients-caught-in-conflict-between-hospital-and-nursing-homes/>

Harold Van Houtven, C., DePasquale, N., & Coe, N. B. (2020). Brief Report: Essential Long-Term Care Workers Commonly Hold Second Jobs and Double- or Triple-Duty Caregiving Roles. *Journal of the American Geriatric Society* (forthcoming).

Harrington, C., Schnelle, J. F., McGregor, M., & Simmons, S. F. (2016). The Need for Higher Minimum Staffing Standards in U.S. Nursing Homes. *Health Services Insights*, 2016(9), 13-19.

Medicare and Medicaid Programs, Basic Health Programs, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program, 85 Fed. Reg. 27550 (proposed May 8, 2020)(to be codified at 42 C.F.R. pts. 409, 410, 412, 413, 414, 415, 424, 425, 440, 483, 484, 600).

Medicare and Medicaid Programs; Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Efficiency, and Transparency, 84 Fed. Reg. 34737 (proposed July 18, 2019)(to be codified at 42 C.F.R. pts. 410, 482, 483, 485, 488).

Quality Care for Nursing Home Residents and Workers During COVID-19 Act of 2020, H.R. 6698, 116th Cong. (2020).

Sklar, T. & Terry, N. (2020). States are Making it Harder to Sue Nursing Homes over COVID-19: Why Immunity from Lawsuits is a Problem. *The Conversation*. Retrieved June 12, 2020, from <https://theconversation.com/states-are-making-it-harder-to-sue-nursing-homes-over-covid-19-why-immunity-from-lawsuits-is-a-problem-139820>

U.S. Dep't of Health & Human Services (2020). Press Release: HHS Announces Nearly \$4.9 Billion Distribution to Nursing Facilities Impacted by COVID-19. Retrieved June 12, 2020, from <https://www.hhs.gov/about/news/2020/05/22/hhs-announces-nearly-4.9-billion-distribution-to-nursing-facilities-impacted-by-covid19.html?amp>

PART 4

**Assuring Access to Medicines
and Medical Supplies**

Summary of Recommendations for Assuring Access to Medicines and Medical Supplies

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Assuring Access to Medicines and Medical Supplies* address matters related to drug and vaccine development and production and distribution of medical supplies. Recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal and state guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic.

Action at the Federal Level

- To prevent and manage shortages of PPE and other essential medical supplies
 - o The president should empower and equip competent career government staff with the necessary resources to fully use federal emergency and DPA authority to
 - Identify and assess the availability of all basic medical equipment required for COVID-19 response
 - Assess domestic and international production capacity and supply chains
 - Use investment and purchasing to incentivize manufacturers to add necessary capacity
 - Develop and implement a strategy for federal procurement and need-based distribution to states (Sinha, PPE; Anderson and Burris, Assuring)
 - o Congress should
 - Fund and require HHS to implement and manage the long-term staff and infrastructure to monitor, track, and proactively address deficiencies in the supply chain for essential medical supplies (Anderson and Burris, Assuring)
 - Fund BARDA and DARPA to conduct research into more sustainable forms of PPE, including N95 masks designed for sterilization and re-use (Sinha, PPE)
 - Mandate that any PPE-related innovation from BARDA and DARPA not be held in confidence as a state secret (Sinha, PPE)
 - Immediately fund the purchase personal protective equipment and test kits—including more accurate, less invasive tests that provide faster results—for distribution to state and local governments (Wiley, Federalism)
 - Reaffirm the enduring role of the SNS as the primary resource for the nation during emergency surges in demand (Anderson and Burris, Assuring), and replace permissive language in the Public Health Services Act with mandatory language to direct the Department of Health and Human Services to support state and local efforts by acquiring and distributing supplies via the Strategic National Stockpile (Wiley, Federalism)
- o HHS should
 - Properly implement and manage the long-term staff and infrastructure to monitor, track, and proactively address deficiencies in the supply chain for essential medical equipment (Anderson and Burris, Assuring)
 - Promulgate, with real attention, new regulations on emergency supply chain management including developing and implementing “stress tests” for supply chains for key products, and reorganize accordingly (Anderson and Burris, Assuring)
 - Immediately and substantially increase stores of traditional and alternative PPE in the SNS (as it has done for potential treatments for COVID-19) (Sinha, PPE)
- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund, and should expand support for the National Hospital Preparedness Program, and the Strategic National Stockpile (Gable, Crisis)
- HHS OCR should develop, expand, and update guidance for the allocation of scarce resources and crisis standards of care consistent with federal antidiscrimination laws (Gable, Crisis)
- To enable the development of high-quality alternative PPE
 - o FDA, NIOSH, and OSHA should finalize (or otherwise make permanent) all draft COVID-19 guidance documents and standards[1][2]. Relevant guidance documents include, but are not limited to:
 - Alternative sources of PPE, especially PPE produced via 3D-printing techniques

- Development and testing of alternative PPE
- Sterilization and reuse of traditional and alternative PPE
- o The FDA should update PPE-related guidance in the following areas:
 - A new premarket evaluation process for alternative PPE to be used in emergent situations, prior to the declaration of an emergency
 - A finalized “Appendix A” list of authorized respirators
 - An amended EUA on imported face masks to penalize identifiable manufacturers of counterfeit products under misbranding authority
 - The role of FDA and NIOSH in testing newly fabricated PAPRs (Sinha, PPE)
- To assure that vaccines and drugs are safe, effective and trusted by the public, FDA should
 - o Decline to authorize EUAs for COVID-19 vaccines
 - o Insofar as FDA considers issuing an EUA for a COVID-19 vaccine, it should be limited to use, on a voluntary basis, to individuals with a documented higher than baseline risk of death or serious injury from COVID-19
 - o Issue EUAs only when they serve public health, as authorized by the FDCA
 - o Clearly communicate and reiterate that EUAs are not “approvals” and that the standard for issuing an EUA does not include a determination that the product has been shown to be safe or effective for its intended purpose
 - o Be as proactively transparent as the law permits it to be in all decisions that FDA makes about COVID-19 countermeasures
 - o Make decisions about which products to authorize or approve for COVID-19 based on the best available public health and scientific evidence, to help ensure better decisions and public trust in those decisions
 - Political pressure on FDA may be particularly acute during pandemics. For this reason, Congress and FDA should consider creating specific processes to protect decision making during pandemics, such as requiring FDA to proactively release detailed information about the basis for its EUA decisions immediately after they are made
 - o Consider routinely requiring patient registries for products that are issued EUAs to help gather information both about patient outcomes and about any disparities in access to such products
 - o Consistent with its obligations under Section 564 of the FDCA, actively and carefully review EUAs, revoking or revising them when needed
 - The results of FDA’s reviews, coupled with a summary analysis of data, should be made public as soon as they are completed
 - In some circumstances, such as COVID-19, a post-market review may be appropriate as frequently as weekly.

The rationale underlying the timing of the post-market reviews should be data-driven and publicly disclosed (Zettler et al., Drug and Vaccine Development)

- Congress should reconsider whether EUAs for vaccines intended for widespread use in healthy people are ever appropriate and consider appropriate revisions to Section 564 of the FDCA (21 USC § 360bbb-3)(Zettler et al., Drug and Vaccine Development)
- To achieve some balance between broad access to patented technologies for COVID-19 response and incentives for future technology development
 - o The federal government, acting through the Centers for Disease Control or another appropriate agency, should assess the patent landscape for technologies critical to COVID-19 response, including the licensing practices of key patent holders, and identify any areas in which the combination of patent protection and a demonstrated unwillingness of patent holders to make their rights available to others could plausibly hinder the rapid development and deployment of technologies necessary to combat the pandemic
 - With respect to such patents, the government should develop and publish a plan for asserting governmental use and march-in rights under 28 USC § 1498 and the Bayh-Dole Act, with the proviso that any patent holder that voluntarily pledges its patents for COVID-19 response on a broad, royalty-free basis (eg, the Open COVID Pledge) would not be subject to such measures
 - o In areas key to COVID-19 response, the government should select technology targets requiring further research and development and develop incentive programs (eg, prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (eg, the Open COVID Pledge) for purposes of COVID-19 response
 - o The government should commit to procuring products and supplies only from entities participating in patent pools (Contreras, Expanding Access)

Action at the State Level

- To improve inter- and intra-state coordination of procurement and distribution of medical supplies, states should
 - o In the long term, use legislation, appropriations and long-term contracts to
 - Establish permanent channels for sourcing essential traditional PPE in times of crisis, independent of federal authorities. States may consider establishing their own stockpiles or engaging in long-term procurement contracts
 - Establish robust community networks for fabricating alternative PPE according to need, including makers, designers, and local businesses that can quickly and efficiently ramp up production (Sinha, PPE; Anderson and Burris, Assuring; see also Gable, Crisis)

- o In the near term, as long as federal coordination lags, continue to formalize and extend interstate cooperation in procurement and sharing of resources including, ultimately, vaccines (Anderson and Burris, Assuring; Wiley, Federalism)
- To protect patients from the risks of unapproved drugs and unproven uses
 - o State officials and agencies, including boards of medicine and pharmacy and public health departments, should clearly communicate to health care institutions, health care professionals, and the public that EUAs are not FDA approvals, the difference between approvals and EUAs, and what is known, and not known, regarding the safety and effectiveness of products available under EUAs
 - o State boards of medicine and pharmacy should discourage off-label use of existing products unless strong evidence supports use for COVID-19 (Zettler et al, Drug and Vaccine Development)
- State legislatures or executive agencies should
 - o Review their crisis standards of care protocols to assure compliance with federal and state antidiscrimination law
 - State law should prohibit medical allocation decision making based on social stigma or stereotypes regarding age, color, criminal history, disability, ethnicity, familial status, gender identity, height, homelessness, immigration status, incarceration status, marital status, mental illness, national origin, poverty, race, religion, sex, sexual orientation, socio-economic status, substance abuse disorder, use of government resources, veteran status, or weight
 - o As necessary, develop and enact in law, regulation or guidelines protocols for crisis standards of care and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies and clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19
 - Developers should seek public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most affected by the consequences of COVID-19 infections and most likely to be disadvantaged by CSC protocols (Gable, Crisis)
- Legislators should
 - o Enact statutory standards and procedures for imposing crisis standards of care that set out when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority
 - o Enact liability shields for health care professionals and institutions following state-adopted and implemented crisis standards of care protocols in good faith for harms arising from decisions allocating scarce medical resources and services (Gable, Crisis)
- To achieve some balance between broad access to patented technologies for COVID-19 response and incentives for future technology development, state governments should
 - o Select technology targets in areas key to COVID-19 response requiring further research and development and develop incentive programs (eg, prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (eg, the Open COVID Pledge) for purposes of COVID-19 response
 - o Commit to procuring products and supplies only from entities participating in patent pools (Contreras, Expanding Access)

COVID-19: State and Local Responses to PPE Shortages

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SUMMARY. In mid-March, healthcare workers on social media and elsewhere sounded the alarm: #GetMePPE. This public plea was in response to shortages of personal protective equipment (PPE) at many hospitals, coinciding with surges in hospital emergency department and intensive care unit capacity due to COVID-19. Within days, the Strategic National Stockpile of PPE was depleted; states, localities, and hospitals had to act urgently to procure PPE and reuse or extend the use of existing PPE. A true cottage industry emerged, consisting of a network of designers, makers, engineers, and healthcare workers focused on designing and producing high-quality PPE to address urgent needs. Devices such as face shields were designed to protect healthcare workers from mucous membrane exposure. As N95 respirator masks became scarce, techniques for sterilization were developed, as were methods for ensuring a qualitative fit after multiple rounds of sterilization. Alternatives to N95 masks, known as powered air purifying respirators (PAPRs), were developed from scratch. Finally, ventilators and ventilator parts were produced in an effort to maximize resources during peak waves of COVID-19. The FDA released a series of guidance documents, accompanied by permissive emergency use authorizations (EUAs), to address the manufacture and use of PPE in healthcare settings. This article reviews actions taken by the FDA in response to the PPE shortage, evaluates the impact of local manufacturing of PPE in one U.S. state (Massachusetts), and offers solutions for federal and state policymakers to ensure robust state and community-level responses to shortages in the future.

Introduction

As the COVID-19 pandemic spread across the globe in early 2020, it became increasingly clear that the United States was unprepared for the accompanying surge in healthcare utilization. One of the less-anticipated challenges was—and continues to be—access to sufficient quantities of personal protective equipment (PPE) for healthcare workers and other essential personnel. Unlike in blockbuster movies about pandemics, where healthcare workers are portrayed in highly-protective forms of PPE resembling spacesuits, healthcare workers in early COVID-19 “hotspot” areas like New York City were told to reuse filtering facepiece respirators (FFRs) like N95-rated respirators (N95 masks), which are designed for single use and do not have clearly established decontamination protocols. Hospitals and other institutions that had previously been using one set of PPE per patient quickly found themselves in need of replenishment.

With the federal government disinclined to help, state and local governments have turned to community members and academic institutions for assistance (Sinha et al., 2020). Charitable donations of PPE to hospitals and other healthcare settings have made an impact—particularly when collected and distributed in a coordinated fashion. Yet evolving guidance from the Centers for Disease Control and Prevention (CDC) and the Food and Drug

Administration (FDA) has made it difficult to determine whether certain donations, like KN95 masks made in China, are safe for use in healthcare settings (Godoy, 2020).

In response to the shortages, a global network of makers using 3D-printing technology has worked diligently to design and produce PPE for front-line workers. One part of that network, a consortium of academic physicians and scientists at Brigham and Women’s Hospital, Harvard Medical School, and the Massachusetts Institute of Technology has set out to resolve local shortages by designing, manufacturing, and validating alternative PPE for use during the COVID-19 pandemic. This Chapter derives from the author’s experience as the regulatory lead for the Greater Boston Pandemic Fabrication Team (“Pan-Fab,” <https://www.panfab.org/>) and offers suggestions for policymakers looking to augment community-level responses to supply PPE for front-line workers, both for COVID-19 and future pandemics.

Federal Laws and Regulations Governing PPE FDA and NIOSH Regulation of Medical Devices

From basic products like face shields to more complex products like FFRs and powered air purifying respirators (PAPRs), most PPE is regulated by the FDA as a medical device pursuant to authority under the Federal Food, Drug, and Cosmetic Act. Oversight of

medical devices is less rigorous than that of pharmaceuticals, requiring only a demonstration of substantial equivalence—comparable safety and efficacy—to one or more marketed devices. No arduous FDA approval process is required; a 510(k) premarket notification and agency finding of substantial equivalence clears the device for marketing and commercial distribution. Good manufacturing practices require that products have unique device identifiers, so that they can be traced in case of manufacturing flaws and monitored for adverse events. For certain respiratory devices like FFRs and PAPRs, the National Institute of Occupational Safety and Health (NIOSH) must test and certify the product prior to filing a 510(k) premarket notification with the FDA.

OSHA Regulation of Workplace Safety

Under the Occupational Safety and Health Act (OSH Act), the Occupational Safety and Health Administration (OSHA) regulates the safety and health of workplaces, including healthcare facilities. This includes the authority to regulate personal protective equipment (“General Requirements,” 2017). State regulation of workplace safety and health is generally preempted by federal law, but states can submit workplace safety and health plans for approval by OSHA under Section 18(b) of the OSH Act. Once approved, state officials have the ability to regulate workplace safety within their borders, but OSHA can rescind the approval at any time. Finally, the Secretary of HHS has the authority to issue emergency temporary standards to protect workers from new sources of harm (Congressional Research Service, 2020).

PPE and the COVID-19 Pandemic Emergency Regulation of PPE

In his early February declaration of a public health emergency, Secretary of Health and Human Services (HHS) Alex Azar declared that the circumstances warranted emergency use of in vitro diagnostics and other medical devices for responding to COVID-19. Since that time, the FDA has issued several Emergency Use Authorizations (EUAs) that allow non-FDA approved medical products to be used for the COVID-19 response—in the absence of adequate FDA-approved alternatives (U.S. Food and Drug Administration, 2020b). EUAs expire upon resolution of the public health emergency, as determined by the Secretary of HHS. The public health emergency and the EUAs are issued on a temporary basis and must routinely be reassessed and renewed if warranted. The FDA has also issued and frequently updated guidance documents for manufacturers seeking to produce novel medical devices for responding to COVID-19 PPE shortages.

Sourcing of PPE

The Federal government has multiple levers by which it can compel production, acquire, and distribute PPE. The Defense Production Act (DPA) allows the president to commandeer the manufacturing of essential products during national emergencies (discussed elsewhere in this volume). Rather than invoking DPA, the current administration chose to enter into voluntary agreements with industry partners, in volumes insufficient to meet national demand. For example, a production order was placed with 3M in early April for 10 million N95 masks to augment the Strategic National

Stockpile; by one estimate, the United States needs 3.5 billion N95 masks for its COVID-19 response over the next year. The Federal Emergency Management Agency (FEMA), tasked with distribution of PPE from the Strategic National Stockpile, has inadequately supplied states with PPE and other critical medical supplies (U.S. Department of Health and Human Services, 2020).

In the absence of a robust federal response to PPE shortages, states were forced to grapple with PPE shortages on their own. Some governors have issued executive orders requiring public health safety measures for essential businesses, though supplies remain limited and those orders may be preempted by the OSH Act. In particular, state-based PPE mandates are likely preempted by federal law unless states submit plans to OSHA for approval. In Massachusetts, the Emergency Response Team (M-ERT) was established to help coordinate immediate needs for PPE in healthcare facilities (Zeidel et al., 2020). But state efforts were not always successful: Massachusetts was outbid by the federal government for batch PPE procurement, leading the state to join a coalition of states for greater purchasing power. During the early COVID-19 response, many hospitals were left without federal and state assistance and had to fend for themselves. One Massachusetts hospital’s tumultuous path to securing PPE was recently chronicled in the *New England Journal of Medicine* (Artenstein, 2020).

Community Response

Some desperate hospitals and health centers turned to the community for assistance. PPE donations to hospitals began streaming in—organizations like GetMePPE helped to coordinate donations and distribute based on need. Professional societies have also attempted to address inequitable distribution of PPE, particularly to rural physician offices and to physicians and institutions caring for underserved populations. The Massachusetts Medical Society has been active at the state level, and the American Medical Association recently partnered with Project N95 to supply PPE to its physician-members.

In addition, co-creation efforts and distributed production via makers, hobby shops, and small companies have accelerated the production and deployment of certain supplies like PPE. Makers can join or contribute to several initiatives for sourcing medical supplies, and by doing so, form online communities and create academic-public-private partnerships. Several initiatives support makers in creating and providing PPE, including America Makes and the NIH 3-D Print Exchange. Some makers work with groups in healthcare settings, such as Pan-Fab; others act independently, producing products from downloadable templates and shipping or delivering them to hospitals or other healthcare settings. Alternative PPE produced by Pan-Fab and others is intended for use during the current public health emergency only. In order to continue production in non-pandemic times, a manufacturer would need to submit a 510(k) premarket notification and register its facility with the FDA—its production and use during the COVID-19 pandemic cannot otherwise extend beyond the current crisis. Premarket notification and registration may be feasible for small- or medium-sized companies producing PPE, but will not be feasible for an individual maker producing PPE at home.

Filtering Facepiece Respirators

FFRs like N95 masks (named for their N95 NIOSH rating) are a critical component of infection control against contagious respiratory illnesses like COVID-19. N95 masks have three primary properties: (1) the ability to filter out small particles; (2) a tight fit to the face so that inhaled and exhaled air is directed through the filter; and (3) low inhalation resistance so that a user's oxygen supply is not limited. Qualitative fit is evaluated through a process known as fit testing, which ensures that the mask forms a tight seal with the user's face. Quantitative testing evaluates filtration efficiency, confirming that the material filters particles effectively without posing harm to the user. While healthcare institutions are typically equipped to evaluate fit of N95 masks, they are rarely if ever able to measure filtration efficiency.

Imported and Counterfeit Face Masks. In addition to facilitating the manufacture of alternative PPE, the FDA issued EUAs permitting the importation and use of non-NIOSH approved masks that have met functionally equivalent international standards. N95 masks sold in the US are regulated by the FDA and tested to standards set by NIOSH. Similar standards and enforcement mechanisms exist in other industrialized countries, including KN95-rated masks in China and FFP2-rated masks in Europe.

In an effort to clarify matters, the CDC released a list of authorized respirators under the EUA ("Appendix A") on April 3, 2020; no performance testing data was required from respirator manufacturers to corroborate performance claims before inclusion on the list (U.S. Food and Drug Administration, 2020a). In the ensuing weeks, the CDC noted a dramatic increase in counterfeit respirators that misrepresented NIOSH approval, and the CDC and other groups revealed that some respirators labeled as N95, KN95, or FFP2 fail to perform as expected for filtration and fit (Centers for Disease Control and Prevention, 2020). Appendix A has been revised several times since it was first published, creating uncertainty among state officials and hospital administrators as to which face masks are safe for use—particularly KN95 masks.

As imported masks flooded the U.S. market, the CDC and FDA were unprepared to rapidly assess the quality of individual products. Healthcare systems, first responders, and others have received donations of unfamiliar mask models, many of them donated and with unclear supply chain provenance. In April, through a widely-publicized joint effort with the Commonwealth of Massachusetts, New England Patriots owner Robert Kraft used the team plane to retrieve over one million KN95 face masks from China; some were reportedly identified to be counterfeit.

Reuse and Sterilization. As national PPE shortages emerged, methods were developed for sterilizing and reusing PPE. During the COVID-19 pandemic, the FDA issued EUAs for these methods. For instance, Battelle received an EUA on March 29, 2020 for its vaporized hydrogen peroxide sterilization system; the company was subsequently awarded a federal contract of \$415 million on April 13, 2020 to sterilize N95 masks (U.S. Food and Drug Administration, 2020c). Battelle facilities that could sterilize up to 80,000 masks per day at full capacity were established across the country, but the cost per mask was \$3.25 and did not include transportation to and

from the facility. By comparison, the baseline pre-pandemic cost of an N95 mask was approximately \$1.00.


The Pan-Fab team investigated whether a similar product, Steramist (ionized hydrogen peroxide, iHP), could sterilize masks as effectively as the Battelle system (Cramer et al., 2020). The Steramist environment chamber is able to disinfect 7000 masks per day. Importantly, these sterilization chambers are more readily available in animal research facilities at academic medical centers, such as the one at the Dana-Farber Cancer Institute used in the Pan-Fab study. In early March 2020, the Battelle sterilization system received its EUA in a matter of days. In contrast, the manufacturer of Steramist, TOMI Environmental Solutions, has experienced delays in obtaining an EUA for their iHP sterilization process, suggestive of a more judicious review process at the FDA.

Mask Frames. During the H1N1 pandemic of 2009, the CDC and NIOSH relaxed standards for the extended use and reuse of N95 face masks as a result of shortages, but provided no guidance as to how to test the masks over time, instead recommending disposal only when they were visibly soiled. One of the challenges to reusing PPE like N95 masks is that they are manufactured for single use and components can degrade over time. For instance, elastic bands may break, either prior to initial use or upon subsequent reuse. In some cases, the nosepiece may no longer be able to create an effective seal after multiple uses. In others, makeup or skin protectants may disrupt the seal over time. Because fit is essential for proper function of the mask and can deteriorate after repeated use, the Pan-Fab team developed a 3D-printed device that, when placed over certain types of N95 masks, improves qualitative fit of masks, including for individuals who do not typically pass fit testing (McAvoy et al., 2020). Because the mask frame does not touch the face or affect the function of the N95 mask, it is unlikely to need clearance from the FDA or NIOSH.

Alternatives To N95 Masks: Powered Air-Purifying Respirators.

Powered air-purifying respirators (PAPRs) are perhaps the most complex of all respiratory PPE. The apparatus supplies filtered air to the user while preventing exposure to external air. PAPRs have historically been in short supply in hospitals: N95 masks are cheaper and more readily available, whereas PAPRs are expensive, bulky, loud, and have short battery life. Yet in times of PPE shortage, PAPRs may be a sustainable alternative to N95s, particularly in the setting of prolonged shortage. Members of the Pan-Fab team designed and engineered a new PAPR using 3D-printed and other parts. Though PAPRs are required to be NIOSH-tested prior to use, no emergency guidance was available for navigating the design and testing of a fabricated PAPR. Under NIOSH regulation, medical PAPRs are held to the same standards as PAPRs intended for other uses, which are that the device have a P100 rating (filter 100% of particles and be oil proof). This is a higher standard than that of an N95 mask (which filter 95% of particles and are not oil-proof), but the FDA and NIOSH have not weighed in as to whether a lower threshold than P100 might be acceptable for PAPRs intended for use during the COVID-19 pandemic. No EUAs have been granted for PAPRs to date, and it is not clear whether such devices would require an EUA prior to production and widespread implementation.

Other Protective Equipment

Face Shields. One of the earliest work products of Pan-Fab, the face shield was 3D-printed by makers, with iterative improvements made based on clinical feedback from emergency department physicians at Brigham and Women's Hospital (Mostaghimi et al., 2020). Face shields are worn in addition to face masks to limit droplet exposure, particularly during procedures that expose healthcare providers to greater risks, like intubation. Unlike PAPRs, they must be used in conjunction with an N95 mask. The FDA allowed use without regulatory clearance, but no regulatory guidance exists for how to disinfect between uses. There is also no clear guidance as to whether to discontinue use of face shields after the public health emergency ends. 

Recommendations for Action

Federal government:

The Federal government should do everything in its power to expedite production of traditional PPE while streamlining the process for developing and producing high-quality alternative PPE.

- The president should invoke the full authority of the Defense Production Act to bring production of PPE to scale (discussed elsewhere in this volume).
- The Office of the Assistant Secretary for Preparedness and Response (ASPR, within HHS) should immediately and substantially increase the Strategic National Stockpile of traditional and alternative PPE (as it has done for potential treatments for COVID-19) while developing a need-based national dissemination strategy for PPE dissemination to states.
- The secretary of HHS, pursuant to the OSH Act, should issue an emergency temporary standard (ETS) to protect front-line health care workers from exposure to grave danger of from aerosol transmissible diseases like COVID-19 [29 USC 655(c)].
 - o The Heroes Act (H.R.6800, passed by the U.S. House of Representatives in May 2020) would require an OSHA ETS and permanent standard for COVID-19 exposure (a similar clause was removed from the Families First Coronavirus Response Act [P.L. 116-127] prior to passage).
- The FDA, NIOSH, and OSHA should finalize (or otherwise make permanent) all draft COVID-19 guidance documents and standards. Relevant guidance documents include, but are not limited to:
 - o Alternative sources of PPE, especially PPE produced via 3D-printing techniques;
 - o Development and testing of alternative PPE;
 - o Sterilization and reuse of traditional and alternative PPE.
- The FDA should require that manufacturers more comprehensively evaluate alternative PPE products or sterilization methods that have received EUAs and revoke EUAs for products or processes that fall short of appropriate regulatory standards.
- The FDA should update PPE-related guidance in the following areas:
 - o A new premarket evaluation process for alternative PPE to be used in emergent situations, prior to the declaration of an emergency;
 - o A finalized “Appendix A” list of authorized respirators;
 - o An amended EUA on imported face masks to penalize identifiable manufacturers of counterfeit products under misbranding authority;
 - o The role of FDA and NIOSH in testing of newly fabricated PAPRs.
- Congress should appropriate funding to the Biomedical Advanced Research and Development Authority (BARDA) and the Defense Advanced Research Projects Agency (DARPA) for research into more sustainable forms of PPE, including N95 masks designed for sterilization and reuse.
 - o Congress should assure that any PPE-related innovation from BARDA and DARPA is not held in confidence as a state secret.
- established standards for aerosol transmissible diseases.
- States should establish permanent channels for sourcing traditional PPE in times of crisis, independent of federal authorities, and ensure those channels remain viable over time. States may consider establishing their own stockpiles or engaging in long-term procurement contracts.
- States should establish robust community networks for fabricating alternative PPE according to need, including makers, designers, and local businesses that can quickly and efficiently ramp up production. States may establish independent contracting relationships or agree to purchase volumes and prices in advance, and may look to these networks to supply their own stockpiles with alternative PPE.
- States should ensure that all hospitals, healthcare facilities, and physician offices are supplied according to need rather than prestige, financial resources, or political capital.
- States should establish strategies for addressing donated PPE: reliance on donations should be a last resort given challenges in validating donated PPE such as N95 and KN95 masks. A centralized process for evaluating and discarding counterfeit face masks may be the most efficient approach.

State governments:

Suggestions for improving inter- and intra-state coordination of PPE include:

- States should submit their COVID-19 emergency workplace safety and health guidelines to OSHA for review and approval, as required under the Occupational Safety and Health Act for states that choose to develop and enforce their own standards.
 - o Several states have established their own standards for COVID-19, and California and Virginia have

Hospitals:

Hospitals and academic medical centers can take certain actions to ensure adequate supplies of PPE for future surges:

- Hospitals need a permanent central command office, active during public health emergencies but still operational in the interim. Protocols should be rehearsed frequently and updated as needed.

Recommendations for action, continued

- Hospitals need plans to ensure adequate stockpiles of PPE, including strategies for sourcing in the absence of national or state assistance. Advance preparation may require collaboration with the maker community and linking into a national network of makers.
- * Hospitals should develop their own protocols for sterilization and re-use of PPE like N95 masks during surges.
- * Hospitals should evaluate strategies for extending the life of essential PPE like N95 masks by utilizing devices like mask frames.
- * Hospitals should invest in sustainable PPE such as PAPRs, which can help alleviate the impact of N95 mask shortages.

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References

- Artenstein, A. W. (2020). In Pursuit of PPE. *New England Journal of Medicine*, 382(18), e46.
- Centers for Disease Control and Prevention. (2020). Counterfeit Respirators / Misrepresentation of NIOSH-Approval. Retrieved July 29, 2020, from <https://www.cdc.gov/niosh/npptl/usernotices/counterfeitResp.html>
- Congressional Research Service. (2020). Occupational Safety and Health Administration (OSHA): Emergency Temporary Standards (ETS) and COVID-19. Retrieved July 29, 2020, from <https://crsreports.congress.gov/product/pdf/R/R46288>
- Cramer, A. K., Plana, D., Yang, H., Tian, E., Carmack, M., Sinha, M. S., Krikorian, D., Turner, D., Mo, J., Li, J., Gupta, R., Manning, H., Bourgeois, F. T., Yu, S. H., Sorger, P., & LeBoeuf, N. R. (2020). Analysis of the SteraMist Ionized Hydrogen Peroxide Technology in the Sterilization of N95 Respirators and Other PPE: A Quality Improvement Study. *MedRxiv*, (forthcoming.)
- General Requirements, 29 C.F.R. 1910.132 (2017).
- Godoy, M. (2020). A User's Guide To Masks: What's Best At Protecting Others (And Yourself). Retrieved July 29, 2020, from <https://www.npr.org/sections/goatsandsofa/2020/07/01/880621610/a-users-guide-to-masks-what-s-best-at-protecting-others-and-yourself>
- McAvoy, M., Bui, A.-T. N., Hansen, C., Plana, D., Said, J. T., Yu, Z., ... LeBoeuf, N. R. (2020). 3D Printed Frames to Enable Reuse and Improve the Fit of N95 and KN95 Respirators. *MedRxiv*, (forthcoming.)
- Mostaghimi, A., Antonini, M.-J., Plana, D., Anderson, P. D., Beller, B., Boyer, E. W., ... Yu, S. H. (2020). Regulatory and Safety Considerations in Deploying a Locally-Fabricated, Reusable, Face Shield in a Hospital Responding to the COVID-19 Pandemic. *Med*, 1(1), 1-13.
- Sinha, M. S., Bourgeois, F. T., & Sorger, P. K. (2020). Personal Protective Equipment for COVID-19: Distributed Fabrication and Additive Manufacturing. *American Journal of Public Health*, 110(8), 1162-1164.
- United States Department of Health and Human Services. Strategic National Stockpile PPE Distribution Report. Retrieved July 29, 2020, from <https://oversight.house.gov/sites/ democrats.oversight.house.gov/files/documents/SNS%20PPE%20REPORT.pdf>
- U.S. Food and Drug Administration. (2020a). Appendix A: Authorized Imported, Non-NIOSH Approved Respirators Manufactured in China. Retrieved July 23, 2020, from <https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>
- U.S. Food and Drug Administration. (2020b). Emergency Use Authorization. Retrieved July 23, 2020, from <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- U.S. Food and Drug Administration. (2020c). Letter of Authorization: Battelle Decontamination System. Retrieved July 23, 2020, from <https://web.archive.org/web/20200331153258/https://www.fda.gov/media/136529/download>
- Zeidel, M. L., Kirk, C., & Linville-Engler, B. (2020). Opening Up Supply Chains. *New England Journal of Medicine*, 382(21), e73.

Expanding Access to Patents for COVID-19

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SUMMARY. Two competing and linked sets of goals must be addressed when considering patent policy in response to a public health emergency. First is the allocation of existing resources among potential users (hospitals, patients, etc.); second is the creation of new technologies over time (innovation). Patents provide financial incentives to develop new technologies. Yet shortages of patented products often plague crisis response. In the case of COVID-19, allocative goals, particularly satisfying demand for patented medical products (e.g., vaccines, ventilators, PPE, and test kits), may be achieved through governmental interventions such as march-in and governmental use rights (compulsory licensing). But in cases involving the development of new technologies such as vaccines and therapies, incentive structures must be preserved to ensure that the private sector is appropriately motivated to act. In addition to patents, which reward inventors for financially successful innovations, a range of other incentives such as prizes, grants, and subsidies also exist to motivate technological innovation. Incentives like these, coupled with a requirement that resulting discoveries be made available on a broad and open basis, can achieve a balance between allocation and innovation goals. Governments can encourage such measures using both the incipient threat of compulsory licensing and the reward of procurement preferences and other up-front rewards.

Introduction

As COVID-19 spread around the world in early 2020, reports emerged of patent-based threats against manufacturers of products – such as ventilator valves and diagnostic test kits – needed to address the emerging public health crisis. Countries including Germany, France, Israel, and Canada rushed to enact policies to suspend patent rights on vaccines and drugs that could be used to combat the pandemic. Echoing concerns over the inaccessibility of patented vaccine technologies during the SARS and Ebola outbreaks, the World Health Organization (WHO) issued a global call to action, urging governments and the private sector to make patents broadly available in the fight against COVID-19. This Chapter offers a framework for U.S. policymakers as they consider different responses to COVID-19 that may implicate patented technologies.

Patents and the “Access versus Incentives” Tradeoff

Two competing sets of goals must be addressed when considering patent policy. Allocative considerations relate to the distribution of existing resources among potential users. In terms of many patented technologies – e.g., smart phones, aircraft engines, food additives – market forces do a pretty good job of allocating products to those who value them most highly (Landes & Posner, 2003). However, in some cases, simple market action may not achieve desired policy goals. Thus, in the case of patented drugs and health care equipment, considerations such as distributive justice, public health, health equity, and humanitarianism may

lead policymakers to consider interventions designed to promote greater public access to these technologies than the market alone would provide (Outterson, 2005; Lee, 2017). Such interventions may seek to influence product demand (e.g., by subsidizing users through public assistance programs like Medicare and Medicaid) or supply (e.g., by relaxing patent restrictions in order to enable a wider range of suppliers to produce the desired product and offer it at a reduced price (often referred to as compulsory licensing – see below)).

Unlike allocative considerations, dynamic considerations relate to the creation of new technologies over time. Patents are designed to promote innovation, as they provide financial incentives to producers of successful new technologies (at least those that are valued by the market). In addition to patents, other incentive mechanisms exist to encourage innovation, including grants, prizes, and tax incentives (Hemel & Ouellette, 2019). In many cases, several of these incentives can work in tandem (e.g., a grant-funded project that leads to a patentable invention and gives its owner the benefit of a research and development (R&D) tax credit).

These factors do not exist independently of one another, and interventions with respect to one will often affect the other. In some cases, allocative interventions may promote innovation, as when the government subsidizes individual purchases of a patented drug, thereby ensuring patient access to the drug while at the same time rewarding its developer and funding future

research. Yet, in other cases, allocative interventions such as compulsory licensing of patents (described below), may depress an innovator's financial returns and thus reduce its incentive to innovate further. This "access versus incentives" tradeoff is one of the fundamental tensions in intellectual property law (Landes & Posner, 2003; Outterson, 2005; Hemel & Ouellette, 2019). And while such tradeoffs can be justified in the pursuit of legitimate policy goals, it is important for policymakers to understand their nature and extent when considering different policy interventions. This Chapter briefly outlines policy considerations surrounding access and incentive policy interventions pertinent to COVID-19.

Access to Existing Technologies

Once a particular technology exists, there is no further need to incentivize its creation. While it may be desirable to incentivize the creation of improvements and follow-on innovations, policy decisions largely shift to allocative issues (access). Compulsory licensing is a legal mechanism designed to increase access to patented technologies that are being undersupplied by the market (i.e., by the patent holder and its delegates). When imposing a compulsory license, the government effectively requires a patent holder to license its patents to one or more third party manufacturers (usually at a reasonable rate) in order to ensure the continuity of, or an increase in, production and supply of the patented technology.

Unlike many countries, the United States lacks a general statutory framework for the compulsory licensing of patented technologies. However, U.S. law does possess two statutory mechanisms that achieve similar results: federal march-in rights under the Bayh-Dole Act of 1980 (35 U.S.C. § 301 et seq.) and governmental use under 28 U.S.C. § 1498. These two mechanisms are explained below.

March-In Rights under the Bayh-Dole Act

The Bayh-Dole Act of 1980 allows researchers to patent inventions arising from federally-funded research. In return, the Act authorizes the government to exercise so-called 'march in' rights, which compel the owner of any such patent to license it to one or more third parties to the extent necessary, among other things, to address health or safety needs. Numerous petitions have been filed over the years urging federal agencies to exercise their march-in rights under the Act, primarily in cases involving undersupplied or costly pharmaceutical products (Thomas, 2016). To date, however, neither the National Institutes of Health nor any other federal agency has exercised march-in rights under the Act.

While the federal government has been urged to exercise its Bayh-Dole march-in rights in the context of the COVID-19 response (e.g., with respect to vaccine technologies partially funded through federal programs), march-in rights have limitations. Most importantly, they apply only to inventions that were made using federal funding. While many vaccine and drug candidates have arisen from grant-funded university laboratories, a significant amount of biomedical research is conducted in the private sector without federal support. Nevertheless, march-in rights under the Bayh-Dole Act are valuable tools that have the potential to lift patent barriers that might impede the supply of at least some needed goods and services.

Governmental Use

Section 1498 of chapter 28 of the United States Code is not a compulsory licensing law, but a limited waiver by the U.S. government of its sovereign immunity. Under this statute, if the federal government (itself or through its contractors) uses or manufactures a patented invention without the permission of the owner, the owner cannot prevent this use, but may sue the government to recover "reasonable and entire compensation" in the U.S. Court of Federal Claims.

Since its enactment in the early 20th century, the federal government has periodically invoked § 1498 in cases relating to the procurement of military and other equipment. Less frequently, § 1498 has been used to bolster the U.S. supply of drugs and biomedical technologies at prices lower than those charged by patent holders. During a three-year period in the 1960s, the Department of Defense's Military Medical Supply Agency (MMSA) utilized § 1498 to obtain supplies of approximately 50 drugs including the antibiotic tetracycline (Brennan et al., 2016). Though the federal government's use of § 1498 in the pharmaceutical sector declined by the 1970s, the Department of Health and Human Services threatened to invoke the statute in 2001 during the post-9/11 anthrax scare (Brennan et al., 2016). Since then, commentators have proposed using the government's powers under § 1498 to drive down drug prices, but no meaningful utilization of this power has occurred for pharmaceutical products in nearly two decades.

But today, with highly publicized shortages of coronavirus testing kits, facial masks, ventilators, and other critical supplies, the prospect of U.S. government intervention through § 1498 has again gained traction. Section 1498 is a viable mechanism for addressing pandemic-related shortages of any product or service required by the federal government or its contractors.

Commentators who have analyzed the use of § 1498 in connection with the supply of drugs have expressed concern over its limited scope: it only applies to products that are "used or manufactured by or for the United States" (Brennan et al., 2016). In the context of ordinary prescription drugs, this scope might not be broad enough to address the needs of patients whose drug costs are covered by private insurers or health plans. However, the case for government use (and the applicability of § 1498) is stronger in the context of the new coronavirus, which the federal government has declared a national emergency. To the extent the federal government supports, procures, distributes, or administers coronavirus tests, vaccines, treatments, or equipment, such activity could be classified as government use under the terms of § 1498.

Incentivizing the Development of New (and Open) Technologies

While existing technologies are largely (though not entirely) the subject of allocative/access policy interventions, a different calculus exists with respect to as-yet-undiscovered technologies. In these cases, the focus is largely on incentivizing the discovery/creation of the new technology, whether it be a vaccine, a therapeutic, or a medical device. Under ordinary circumstances, patents are effective mechanisms for incentivizing innovation: if granted, they allow the inventor to extract rent from the market

over a multi-year period without close competition. In the case of new prescription drugs, patents enable manufacturers to recoup far more than even their substantial R&D costs. As an intervention, patents do not impose a direct cost on the government (though when government programs purchase patented drugs, they effectively subsidize the inventor), and they generally reward innovations that are successful in the market, eliminating any need to evaluate their quality independently.

However, patents are not always well-calibrated to address social needs. Because their payoff is entirely market-driven, patents incentivize innovations that are likely to be the most lucrative, rather than the most beneficial (hence the tendency of some firms to focus R&D dollars on hair loss treatments and diet pills rather than the eradication of rare diseases). In normal times, governments can seek to guide innovation in socially beneficial directions through a variety of incentive mechanisms: extended periods of market exclusivity for ‘orphan drugs’ directed to rare diseases, research grants targeted at diseases affecting underserved populations, and the like. But in times of emergency, more urgent measures may be required.

Prizes for Open Innovation

In addition to patents, mechanisms such as grants, subsidies, tax incentives, and prizes are used to incentivize innovation. The field of vaccine development offers a useful illustration. In general, vaccine development does not begin until a particular disease strain is identified and recognized as a significant threat (Rutschman, 2018). Patents are often held by diverse entities, making consolidation and effective R&D difficult (Rutschman, 2018; Rutschman 2019). Moreover, vaccines are generally viewed as less profitable than therapeutic drugs, further contributing to their lack of development (Rutschman, 2019; Xue & Ouellette, 2020). And while the number of patents covering vaccine technologies continues to rise, vaccine development is still severely lacking (Rutschman, 2019).

The problem of optimizing vaccine development is dynamic – it relates not to the allocation of existing resources, but to the creation of new ones. To incentivize vaccine development during a major disease outbreak, some commentators have proposed increasing monetary incentives for successfully producing a vaccine in the form of substantial grants, subsidies, or prizes (Lichtman, 2018; Xue & Ouellette, 2020). An important condition of such financial incentives could be a requirement that the awardee make any resulting patents openly available to the public, at least for purposes of COVID-19 response. This requirement would “open” patents for all to use in connection with the present emergency, thus addressing allocative issues, while at the same time permitting the innovator to monetize the invention in other fields and settings (i.e., therapies for diseases other than COVID-19), thereby reducing impediments to dynamic innovation (see, e.g., the Open COVID Pledge (opencovidpledge.org), which allows a patent holder to pledge its technology for free usage in addressing the COVID-19 pandemic, while retaining the right to charge for it elsewhere).

Encouraging Patent Pools

According to some accounts, the largest barrier to effective vaccine development is not insufficient funding during an outbreak (when funding often increases dramatically), but the inability of diverse patent holders to cooperate to productively combine their technologies (Rutschman, 2018; Rutschman, 2019). Accordingly, the twin issues of rights fragmentation and lack of coordination must be addressed (Heller & Eisenberg, 1998).

One well-known method for addressing these related issues is the pooling of patents held by multiple parties – making those patents available as a group to others in the industry. In cases of national emergency, government can encourage (or pressure) private parties to participate in such arrangements. This approach was famously employed in the months prior to U.S. entry into World War I. At that time, “the development of the aircraft industry in the United States was seriously retarded by the existence of a chaotic situation concerning the validity and ownership of important aeronautical patents” (“*MAA v. United States*,” 1933). Fearing that the military would be unable to procure sufficient aircraft, government officials pressured the two leading holders of aviation patents, Wright–Martin and Curtiss–Burgess, to pool their patents with the rest of the industry, thereby alleviating fears throughout the industry that the manufacture of aircraft would lead to litigation.

Patent pools have been proposed in connection with viral outbreaks before, including the 2002–03 SARS outbreak, the 2005 H5N1 influenza outbreak, and the 2009 H1N1 influenza pandemic. Yet, despite the perceived need for aggregation of distributed patent rights in order to combat these diseases, patent pools were never formed for a variety of practical and competitive reasons. In March 2020, the government of Costa Rica called on the WHO to form a patent pool relating to COVID-19. Such a pool, which could address a range of technologies beyond vaccines, would clearly be beneficial to public health.

In the United States, the government could encourage the formation of one or more COVID-19 pools using a carrot and stick approach. On one hand (the stick), government can threaten to enact compulsory licensing mechanisms to compel patent holders to make their patents available to competitors if they do not voluntarily accede to such a pool. On the other hand (the carrot), government can commit to procure relevant medical products only from participants in such pools.

Conclusion

Formulating patent policy to address public health crises involves both allocative considerations as well as incentives for innovation. Neither can be ignored, so solutions that achieve some balance between broad access to patented technologies and incentives for future technology development are needed. Fortunately, several such approaches are available in the area of COVID-19 response and remediation. 🌟

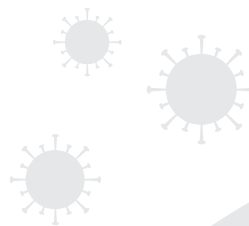
Recommendations for Action

Federal government:

- The federal government, acting through the Centers for Disease Control or another appropriate agency, should assess the patent landscape for technologies critical to COVID-19 response, including the licensing practices of key patent holders, and identify any areas in which the combination of patent protection and a demonstrated unwillingness of patent holders to make their rights available to others could plausibly hinder the rapid development and deployment of technologies necessary to combat the pandemic.
- With respect to such patents, the government should develop and publish a plan for asserting governmental use and march-in rights under 28 U.S.C. § 1498 and the Bayh-Dole Act, with the proviso that any patent holder that voluntarily pledges its patents for COVID-19 response on a broad, royalty-free basis (e.g., the Open COVID Pledge) would not be subject to such measures.
- In areas key to COVID-19 response, the government should select technology targets requiring further research and development and develop incentive programs (e.g., prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (e.g., the Open COVID Pledge) for purposes of COVID-19 response.
- The government should encourage users of complementary patents to form patent pools, and commit to procuring products and supplies only from entities participating in such pools.

State governments:

- In areas key to COVID-19 response, state governments should select technology targets requiring further research and development and develop incentive programs (e.g., prizes, grants, subsidies) to encourage their development, with the proviso that any resulting technologies should be made available under broad, royalty-free terms (e.g., the Open COVID Pledge) for purposes of COVID-19 response.
- The government should encourage users of complementary patents to form patent pools, and commit to procuring products and supplies only from entities participating in such pools.



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References

- Brennan, H., Kapczynski, A., Monahan, C. H., & Rizvi, Z. (2016). A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health. *Yale Journal of Law and Technology*, 18 (2016), 275-354.
- Heller, M. A., & Eisenberg, R. S. (1998). Can Patents Deter Innovation? The Anticommons in Biomedical Research. *Science*, 280(5364), 698-701.
- Hemel, D. J., & Ouellette, L. L. (2019). Innovation Policy Pluralism. *Yale Law Journal*, 128(3): 544-614.
- Landes, W. M., & Posner, R. A. (2003). *The Economic Structure of Intellectual Property Law*. Cambridge, MA: Harvard University Press.
- Lee, P. (2017). Toward Distributive Agenda for U.S. Patent Law. *Houston Law Review*, 55(2), 321-376.
- Lichtman, D. (2018). The Central Assumptions of Patent Law: A Response to Ana Santos Rutschman's IP Preparedness for Outbreak Diseases. *University of California Los Angeles Law Review*, 65(5): 1268-1275.
- Manufacturers Aircraft Ass'n (MAA) v. United States*, 77 Ct. Cl. 481 (Ct. Cl. 1933).
- Outterson, K. (2005). Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets. *Yale Journal of Health Policy, Law, and Ethics*, 5(1), 193-291.
- Rutschman, A. S. (2018). IP Preparedness for Outbreak Diseases. *University of California Los Angeles Law Review*, 65(5): 1200-1267.
- Rutschman, A. S. (2019). The Vaccine Race in the 21st Century. *Arizona Law Review*, 61(4), 729-770.
- Thomas, J. R. (2016). March-In Rights Under the Bayh-Dole Act, Congressional Research Service Report 7-5700 (Aug. 22, 2016). Retrieved July 9, 2020, from <https://fas.org/sgp/crs/misc/R44597.pdf>
- Xue, Q. C., & Ouellette, L. L. (2020). Innovation Policy and the Market for Vaccines. *Journal of Law and the Biosciences* (forthcoming).

Drug and Vaccine Development and Access

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SUMMARY. This Chapter explains how drugs and vaccines for COVID-19 can reach the market in the United States. As is always true, drug and vaccine manufacturers may seek U.S. Food and Drug Administration (FDA) approval of their products via traditional approval mechanisms and drug manufacturers may offer pre-approval access under the expanded access or right to try pathways. In a public health emergency like COVID-19, an additional mechanism is also available: the Emergency Use Authorization (EUA) pathway. This Chapter (1) assesses how FDA has used its EUA authorities for COVID-19 drugs thus far, (2) considers how FDA has balanced the need for robust evidence of safety and effectiveness for COVID-19 pharmaceuticals against the urgent need to speed patients' access amid the clinical and political realities of the pandemic, and (3) highlights considerations specific to vaccines should FDA be faced with a request to issue an EUA for a COVID-19 vaccine. The Chapter concludes with recommendations for policymakers and regulators at the federal and state levels. The recommendations aim to improve public understanding of the regulatory process for COVID-19 drugs and vaccines, protect scientific decision making from undue political pressure, and ensure that manufacturers develop robust evidence of safety and effectiveness—and ultimately safe and effective COVID-19 countermeasures.

Introduction

This Section briefly explains the typical regulatory processes for U.S. Food and Drug Administration (FDA) approval of drugs and vaccines and for pre-approval access for seriously ill patients, absent a public health emergency. It then explains the additional “emergency use authorization” (EUA) mechanism that is available during public health emergencies, such as the COVID-19 pandemic. Although these authorities make FDA the primary gatekeeper for drugs and vaccines in the United States, this Section highlights the gatekeeping role that states also can play through their authority to regulate medical practice.

FDA Approval and Pre-Approval Access

Before a new drug or vaccine may be distributed in interstate commerce in the United States, FDA must approve the product as safe and effective for its specific intended use. Although different statutory provisions govern drug (21 U.S.C. § 355(d)) and vaccine approvals (42 U.S.C. § 262(a)), FDA generally interprets the approval standards for both products to be the same, including requiring that there be “substantial evidence” of effectiveness. To make the necessary showing of safety and effectiveness, drug and vaccine manufacturers typically generate a significant amount of information about their products, starting with pre-clinical testing

in laboratories and animals, and then—if scientifically valuable and ethically permissible—proceeding to three phases of clinical trials in humans, studying the product for the specific use for which approval is sought.

This process serves FDA’s mission to protect and promote the public health in various ways, including helping to protect patients and consumers from unsafe and ineffective products. It also helps to ensure that necessary information about the effects of drugs and vaccines is generated and encourages beneficial innovation by incentivizing the development of products that actually work (Eisenberg, 2007). But this process takes significant time, and some argue that it delays patient access (though it is only in hindsight that we can know access was delayed to a safe and effective product).

There are ways that patients can access products for uses that FDA has not approved, or products that are not FDA-approved for any use. If necessary to ensure that a drug or vaccine’s benefits outweigh its risks, FDA can require a risk mitigation program—known as a Risk Mitigation and Evaluation Strategy (REMS)—which can limit the ways the approved product is used in medical practice (21 U.S.C. § 355-1). Even so, once FDA has approved a product for one use, health care professionals are generally free to prescribe

and dispense it for any use, including unapproved uses (known as “off-label” uses) unless restricted by law or regulation. Within this regulatory gap, state tort law and medical board oversight serve as mechanisms that afford legal and disciplinary recourse should a health care professional fail to exercise reasonable medical judgment in prescribing a product for an off-label use. Additionally, recognizing that patients who face serious illnesses without good treatment options are sometimes willing to accept significant risk or uncertainty, Congress and FDA have created various pathways for manufacturers to provide patients wholly unapproved, experimental products outside of clinical trials for treatment purposes. One long-standing form of such pre-approval access is “expanded access,” which requires authorization by FDA, a statement explaining why the patient needs access, and the manufacturer’s willingness to provide the product, among other things. In May 2018, Congress enacted the federal Right to Try Act, creating a separate pathway for pre-approval access for certain patients and drugs that does not require FDA authorization (Fernandez Lynch et al., 2018).

FDA’s Power to Issue Emergency Use Authorizations During Public Health Emergencies

All of the above-described processes for developing and accessing drugs and vaccines remain available during public health emergencies. Manufacturers may seek FDA approval for drugs or vaccines for COVID-19 with clinical trial data showing substantial evidence of effectiveness (and if necessary to ensure that benefits outweigh risks, FDA could require REMS for COVID-19 drugs or vaccines). Likewise, manufacturers may provide COVID-19 patients pre-approval access to experimental products through expanded access, as Gilead Sciences did with remdesivir early in studying the drug for COVID-19, or through the right to try pathway. After permitting expanded access for remdesivir, Gilead obtained an EUA for the drug and is now winding down its expanded access program (Gilead, 2020). Health care professionals also generally may prescribe and dispense already-approved products for COVID-19. For example, based on reports of new research suggesting dexamethasone, a long-approved corticosteroid, can reduce mortality in certain severely-ill COVID-19 patients, health care professionals increased off-label use of the drug.

In addition to these mechanisms, in 2004 Congress created the EUA pathway for FDA to authorize pre-approval use of medical products during public health emergencies. Specifically, Section 564 of the Federal Food, Drug, and Cosmetic Act (FDCA) allows FDA to issue EUAs authorizing the distribution of unapproved medical products, including drugs, devices, and vaccines, when the secretary of the Department of Health and Human Services (HHS) determines there is a “public health emergency, or a significant potential for a public health emergency” (21 U.S.C. § 360bbb-3). Secretary Alex Azar issued such an emergency declaration for COVID-19 on February 4, 2020. FDA can also issue EUAs for unapproved uses of already-approved products. Even though health care professionals can prescribe and dispense products for off-label uses without such an authorization, in the absence of an EUA the federal government could not stockpile and distribute products for off-label uses through the Strategic National

Stockpile, and liability protections for manufacturers and health care professionals under the Public Readiness and Emergency Preparedness Act may not be available.

For FDA to issue an EUA, whether for an unapproved product or an off-label use of an approved product, various criteria must be met. These include that the manufacturer shows that “it is reasonable to believe” “the product may be effective” for the relevant condition—a bar that is decidedly lower than the “substantial evidence” of effectiveness required for FDA approval. FDA may impose restrictions on products through EUAs, including requiring information collection through patient registries or restricting who may administer the product and to what categories of patients. EUAs are time-limited—they only remain in effect during the public health emergency. Additionally, the FDCA requires FDA to “periodically” review the EUAs that it has issued and authorizes FDA to revoke or revise EUAs at any time if appropriate to protect public health or safety. FDA, thus, has broad power to shape how drugs and vaccines distributed under EUAs are used, and can change conditions or revoke permission to distribute more easily than it can for approved drugs and vaccines.

For each pathway to distribute drugs and vaccines, FDA typically decides whether a product meets relevant standards and determines any conditions on authorization. Given the political nature of responses to public health emergencies, however, it is important to understand that FDA is an agency within HHS and federal law expressly authorizes the HHS secretary, a member of the president’s cabinet—and not FDA—to make these decisions. The secretary delegates that decision-making authority to FDA and rarely has overridden an FDA decision about product approval. But it has happened at least once. In 2011, then-Secretary Kathleen Sebelius directed FDA to decline to approve levonorgestrel (Plan B One Step) as an over-the-counter emergency contraceptive for all ages, notwithstanding FDA’s determination that the scientific evidence supported approval (Heinzerling, 2014).

The States’ Role

Although FDA (or HHS) plays the primary role in determining which drugs and vaccines may be distributed and used in the United States, states also can play a role in determining COVID-19 patients’ access to these products. State boards of medicine and pharmacy may use their authority to regulate medical practice in ways that restrict off-label uses of already-approved products. For example, in March 2020, there were concerns about shortages of chloroquine and hydroxychloroquine—drugs approved for malaria, lupus, and rheumatoid arthritis but touted as having potential for COVID-19—in part because of reports that health care professionals were hoarding the drugs. In response, some states (and the District of Columbia) limited off-label prescribing or dispensing of the drugs for COVID-19 and took steps to communicate the lack of reliable evidence demonstrating their effectiveness for COVID-19 (AMA, 2020).

Although it has not yet happened for COVID-19 drugs or vaccines, states might also try to use their authority to regulate medical practice to completely prohibit use of an FDA-authorized COVID-19

product (e.g., by prohibiting prescribing or dispensing of a particular drug because in the state's view it is not effective) or permit access to a product that lacks any FDA authorization at all (e.g., because in the state's view FDA set the bar for effectiveness too high). Such efforts may be less likely than limits on product use, however, because state prohibitions on FDA-authorized products may be preempted and state laws or regulations more permissive than federal ones may be without practical effect, as states cannot exempt drug and vaccine manufacturers from applicable federal requirements (Zettler, 2017).

Assessing the Regulatory Approach During the COVID-19 Pandemic

In a global public health emergency, like the COVID-19 pandemic, FDA is faced with an undeniably difficult task. On one hand, developing rigorous evidence of products' safety and effectiveness is no less important—rather it is equally, if not more, important (London & Kimmelman, 2020). Generating this evidence will take time. Pre-approval access, including via EUAs, has the potential to interfere with this necessary evidence generation by making it difficult to enroll participants in clinical trials. On the other hand, there is an urgent need to move as quickly as possible. The addition of the EUA mechanism to the FDCA arguably reflects a societal decision that FDA ought to have flexibility to lower standards of safety and effectiveness during public health emergencies to speed access to promising, but unproven, products. FDA is likely to face tremendous political pressure—whether from the White House, HHS, Congress, industry, patients, or other stakeholders—to use that flexibility, and may lose public trust if the agency is viewed as unresponsive to patients' concerns. This Section examines how FDA has balanced these sometimes-competing societal interests and operated amid these political realities during the COVID-19 pandemic thus far.

Balancing Evidence and Access

The federal government, including FDA, has taken some beneficial steps to exercise flexibility and proactively speed the development of promising COVID-19 drugs and vaccines. For example, the federal government created "Operation Warp Speed," a public-private partnership of industry and government representatives working together on medical product development, currently prioritizing vaccines. FDA also has issued dozens of guidance documents explaining the agency's thinking on various issues relating to drugs and biological products for COVID-19. Such guidance documents can help clarify what is needed to bring a drug or vaccine to market. As a final example, FDA has made use of the flexibility that the EUA mechanism offers by issuing, and revoking, EUAs. As of the time of writing, the agency has issued three EUAs for drugs to treat COVID-19—for hydroxychloroquine (on March 28, 2020), chloroquine (on March 28, 2020), and remdesivir (on May 1, 2020)—and revoked two of the EUAs, for hydroxychloroquine and chloroquine, on June 15, 2020. The EUA still in effect for remdesivir is based in part on the results of a randomized, double-blind, controlled clinical trial in 1,063 hospitalized subjects with severe COVID-19, showing a statistically significant reduction in recovery time for those receiving remdesivir (Beigel et al., 2020).

At the same time, there is room for improvement, particularly with respect to public understanding of EUAs, implementation of FDA's EUA authorities, and providing equitable access to COVID-19 countermeasures. For example, although FDA generally distinguishes between EUAs and approvals in its communications, some media reports continue to equate EUAs with FDA approval, including by reporting that FDA "approved" the drugs for which it issued EUAs. It is critical that policymakers, health care professionals, and the public understand that EUAs are a form of pre-approval access, and that products issued EUAs are not necessarily safe or effective countermeasures for COVID-19. Misunderstandings about what an EUA signifies could drive inappropriate policy decisions or undermine public trust in FDA decisions when products issued EUAs prove ineffective or unsafe.

Another major concern is that FDA, perhaps driven by political pressure, may too freely issue EUAs for COVID-19 countermeasures, even judged against the relatively low statutory standard for issuing EUAs. The now-revoked EUAs for hydroxychloroquine and chloroquine provide apt examples. That the EUAs were ultimately revoked is not in and of itself troubling. Because the EUA mechanism is designed to permit FDA to authorize products with less evidence than is required for approvals, we should expect that FDA will authorize products that, once placed on the market, no longer meet the criteria for an EUA (or ultimately prove unsafe or ineffective), and FDA should revoke EUAs when evidence warrants such action. A revocation reflects the uncertainty surrounding safety and effectiveness of countermeasures that receive an EUA, along with the iterative nature of EUA issuance and oversight. In the case of hydroxychloroquine and chloroquine, however, FDA's original decision to issue the authorizations rested on a particularly shaky foundation: limited data of effectiveness from one randomized pilot study of 30 subjects that found little to no effect of the drugs in COVID-19, and an open-label, non-randomized study in 26 subjects that was later discredited (Hirji et al., 2020). FDA also issued the EUAs notwithstanding several known risks of the drugs—which were already approved for other uses—including risks of serious heart arrhythmias. Moreover, FDA issued the EUAs only nine days after the president publicly touted the drugs as COVID-19 countermeasures and, according to a whistleblower complaint from the former director of the Biomedical Advanced Research and Development Authority, at the secretary of HHS's direction—raising significant concerns about political interference in public health decision making (Wamsley, 2020). Similarly, although FDA has not yet faced the question of whether to issue an EUA for a COVID-19 vaccine, concerns about political interference in such a decision have been raised, particularly if an EUA application is under review shortly before the November 2020 election (Joffe & Fernandez Lynch, 2020).

To be sure, concerns about tainted decision making are not limited to the EUA context. For example, the appointed "chief advisor" for Operation Warp Speed stepped down as a board member for Moderna, a company with one of the leading COVID-19 vaccine candidates, to take the position. He, however, reportedly kept his stock in Moderna—valued at over \$10 million—until a senator publicly called for him to divest it, raising questions about financial

conflicts of interest within Operation Warp Speed. Conflicts of interest are particularly troubling in health and public health decision making, especially during a raging and unpredictable pandemic where few countermeasures exist (Sagonowsky, 2020).

Yet another major concern is how to provide fair and equitable access to COVID-19 countermeasures once they are available under an EUA or an approval (Gostin et al., 2020). For example, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices has been considering whether and how to prioritize COVID-19 vaccine access for essential workers and high-risk sub-populations that have been disproportionately affected by COVID-19 and an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine and the National Academy of Medicine is developing a framework for equitable vaccine distribution to aid policymakers (National Academies, 2020; Twohey, 2020). Many aspects of product access, such as ensuring the affordability of countermeasures and developing logistical arrangements for fair distribution, generally fall outside FDA's purview and likely require intragovernmental and cross-sector coordination. But there are steps that FDA might take to use the authorities that it does have to further the goal of equitable access. For instance, Sarpatwari and colleagues argued that by revising the EUA for remdesivir to require a registry that collects information on patient demographics (among other things), FDA could use its existing authority to enable better tracking of access disparities for that drug (Sarpatwari et al., 2020).

Special Considerations for Vaccines

An EUA for a COVID-19 vaccine would pose many of the same issues as those posed by drug EUAs, as well as additional issues specific to vaccines (Joffe & Fernandez Lynch, 2020; Lurie et al., 2020). A drug that is issued an EUA is typically administered to a sick person with no other treatment options, whereas a vaccine is administered to a healthy person. This difference in health status alters the ethical and clinical risk-benefit calculus. A COVID-19 vaccine also may be used widely across the population in individuals of varying ages and co-morbidities. Moreover, any COVID-19 vaccine will be introduced against the background of existing vaccine-hesitancy, and creating and maintaining public trust in FDA's decision making will be more difficult, if not impossible, in the absence of robust data (Parasidis, 2016).

Vaccine research and development takes time. The quickest vaccine to come to market was the mumps vaccine, which took four years from the time virus samples were collected to FDA approval. Most vaccines take a decade or longer to develop, due to the intricacies in honing the vaccine formula to assess safety and effectiveness, and to ensure that the vaccine provides sufficient antibodies to protect against the virus over time. Death or serious side effects from a COVID-19 vaccine would likely cause mass panic amongst the public and drive people away from vaccination—particularly if the COVID-19 vaccine were not supported by robust evidence demonstrating its safety and effectiveness. Although not perfectly analogous for various reasons, one worthwhile example to consider is the 1976 swine flu vaccination program. The swine flu vaccine was rushed to market to address a public health

emergency. Although an outbreak of swine flu did not materialize, the vaccine itself caused dozens of deaths and thousands of vaccine-induced injuries, including paralysis (Parasidis, 2017).

For all of these reasons, developing rigorous evidence of safety and effectiveness, and developing such evidence across all sub-populations for which a vaccine is intended, will be particularly critical before distributing a COVID-19 vaccine. Consistent with this idea, in June 2020 FDA issued a guidance document on COVID-19 vaccines that, while not foreclosing the possibility of EUAs, emphasized the importance of “completion of large randomized clinical efficacy trials” (FDA, 2020).

Insofar as individuals may fall into a high-risk category of death or serious injury from COVID-19, they may be willing to voluntarily accept inoculation with a vaccine for which there is only minimal data on safety and efficacy (Lurie et al., 2020). The normative basis for this predicament assumes that no effective treatment for COVID-19 is available. But even if FDA were to issue an EUA to facilitate voluntary access to an unapproved vaccine, use of such vaccine must be entirely voluntary. We concur with the policy proposals set forth by Mello and colleagues, who argue that the fact that a COVID-19 vaccine has been authorized for use—via an EUA or otherwise—is an insufficient basis for mandatory vaccination; as a matter of public health ethics, mandates should be viewed as a last resort and used only if several other measures are first exhausted and appropriate risk mitigation procedures have been implemented (Mello et al., 2020). 🦠

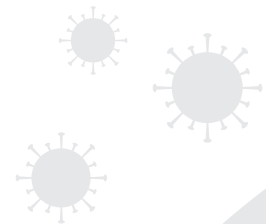
Recommendations for Action

Federal government:

- FDA (and others in the federal government) should clearly communicate and reiterate that EUAs are not “approvals” and that the standard for issuing an EUA does not include a determination that the product has been shown to be safe or effective for its intended purpose.
- For all decisions that FDA makes about COVID-19 countermeasures, the agency should be as proactively transparent as the law permits it to be. Such transparency will help the public understand the agency’s reasoning and what is known about the safety and effectiveness of COVID-19 countermeasures, as well as encourage public trust in agency decision-making. Subsequent recommendations provide specific examples of the kinds of information that the agency should proactively disclose.
- FDA should make decisions about which products to authorize or approve for COVID-19 based on the best available public health and scientific evidence, to help ensure better decisions and public trust in those decisions. Although regulatory decisions about drugs and vaccines should always be made in this manner, political pressure on FDA, whether from Congress, the White House, HHS, industry, patients, or others, may be particularly acute during pandemics. For this reason, Congress and FDA should consider creating specific processes to protect decision making during pandemics, such as requiring FDA to proactively release detailed information about the basis for its EUA decisions immediately after they are made. Ultimately, Congress should consider making FDA a stand-alone agency, outside of HHS (Califf et al., 2019).
- FDA should issue EUAs judiciously. The FDCA permits, but does not require, FDA to issue an EUA when the specified criteria are met. The agency retains flexibility to determine that an EUA is not appropriate for the public health even when all statutory criteria are met.
- FDA should consider routinely requiring patient registries for products that are issued EUAs to help gather information both about patient outcomes and about any disparities in access to such products (Sarpatwari et al., 2020).
- Consistent with its obligations under Section 564 of the FDCA, FDA should actively and carefully review EUAs, revoking or revising them when needed. The results of FDA’s reviews, coupled with a summary analysis of data, should be made public as soon as they are completed. In some circumstances, such as COVID-19, a post-market review may be appropriate as frequently as weekly. In other instances, more time between reviews may be appropriate. The rationale underlying the timing of the post-market reviews should be data-driven and publicly disclosed.
- FDA should decline to authorize EUAs for COVID-19 vaccines. Insofar as FDA considers issuing an EUA for a COVID-19 vaccine, it should be limited to use, on a voluntary basis, to individuals with a documented higher than baseline risk of death or serious injury from COVID-19. Issuance of an EUA for a vaccine that can be used across the entire population may create unnecessary risks to healthy individuals, and may delay or prevent completion of clinical trials on vaccine safety and efficacy.
- Congress should reconsider whether EUAs for vaccines intended for widespread use in healthy people are ever appropriate and consider appropriate revisions to Section 564 of the FDCA (21 U.S.C. § 360bbb-3).

State governments:

- State officials and agencies, including boards of medicine and pharmacy and public health departments, should clearly communicate to health care institutions, health care professionals, and the public that EUAs are not FDA approvals, the difference between approvals and EUAs, and what is known, and not known, regarding the safety and effectiveness of products available under EUAs.
- State boards of medicine and pharmacy should discourage off-label use of existing products unless strong evidence supports use for COVID-19.



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References

- American Medical Association (AMA)(2020). Boards of Pharmacy and Other Actions Relating to COVID-19 Prescribing. Retrieved July 13, 2020, from <https://www.ama-assn.org/system/files/2020-04/board-of-pharmacy-covid-19-prescribing.pdf>
- Beigel, J. H., Tomashek, K. M., Dodd, L. E., Mehta, A. K., Zingman, B. S., Kalil, A. C., ... Lane, H. C. (2020). Remdesivir for the Treatment of Covid-19—Preliminary Report. *New England Journal of Medicine*. Retrieved July 13, 2020, from <https://doi.org/10.1056/NEJMoa2007764>
- Califf, R. M., Hamburg, M., Henney, J. E., Kessler, D. A., McClellan, M., von Eschenbach, A. C., & Young, F. (2019). Seven Former FDA Commissioners: The FDA Should Be An Independent Federal Agency. *Health Affairs*, 38(1), 84-86.
- Eisenberg, R. S. (2007). The Role of the FDA in Innovation Policy. *Michigan Telecommunications and Technology Law Review*, 13(2), 345-388.
- Fernandez Lynch, H., Zettler, P. J., & Sarpatwari, A. (2018). Promoting Patient Interests in Implementing the Federal Right to Try Act. *Journal of the American Medical Association*, 320(9), 869-870.
- Gilead Sciences (Gilead)(2020). Emergency Access to Remdesivir Outside of Clinical Trials. Retrieved July 13, 2020, from <https://www.gilead.com/purpose/advancing-global-health/covid-19/emergency-access-to-remdesivir-outside-of-clinical-trials>
- Gostin, L. O., Friedman, E. A., & Wetter, S. A. (2020). Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically. *Hastings Center Report*, 50(2), 8-12.
- Heinzerling, Lisa. (2014). The FDA's Plan B Fiasco: Lessons for Administrative Law. *Georgetown Law Journal*, 102(4), 927-990.
- Hirji, Z., Vergano, D., & Leopold, J. (2020). Internal FDA Documents Show How Little Evidence The Agency Had Before Allowing Malaria Drugs To Be Used To Treat COVID-19. Retrieved July 13, 2020 from BuzzFeed News, <https://www.buzzfeednews.com/article/zahrahirji/fda-eua-hydroxychloroquine-chloroquine>
- Joffe, S., & Fernandez Lynch, H. (2020). Opinion: The FDA Should Not Rush a Covid-19 Vaccine. *Washington Post*. Retrieved July 13, 2020, from <https://www.washingtonpost.com/opinions/2020/06/02/fda-should-not-rush-covid-19-vaccine/>
- London, A. J., & Kimmelman, J. (2020). Against pandemic research exceptionalism. *Science*, 368(6490), 476-477.
- Lurie, N., Sharfstein, J. M., & Goodman, J. L. (2020). The Development of COVID-19 Vaccines: Safeguards Needed. *Journal of the American Medical Association*. Retrieved July 27, 2020, from <https://doi.org/10.1001/jama.2020.12461>
- Mello, M. M., Silverman, R. D., & Omer, S. B. (2020). Ensuring Uptake of Vaccines against SARS-CoV-2. *New England Journal of Medicine*. <https://doi.org/10.1056/NEJMp2020926>
- National Academies (2020). *A Framework for Equitable Allocation of Vaccine for the Novel Coronavirus*. Retrieved July 27, 2020, from <https://www.nationalacademies.org/our-work/a-framework-for-equitable-allocation-of-vaccine-for-the-novel-coronavirus>
- Parasidis, E. (2016). Public Health Law and Institutional Vaccine Skepticism. *Journal of Health Politics, Policy and Law*, 41(6), 1137-1149.
- Parasidis, E. (2017). Recalibrating Vaccination Laws. *Boston University Law Review*, 97(6), 2153-2242.
- Sagonowsky, E. (2020). "Warp Speed" Head Slaoui, Challenged for "Huge Conflict Of Interest," Sells Off \$12.4M in Moderna Stock. Retrieved July 13, 2020 from FiercePharma, <https://www.fiercepharma.com/pharma/warp-speed-head-slaoui-divests-12-4m-moderna-holdings-to-avoid-conflict-interest>

Sarpatwari, A., Kaltenboeck, A., & Kesselheim, A. S. (2020). Missed Opportunities on Emergency Remdesivir Use. *Journal of the American Medical Association*. Retrieved July 13, 2020, from <https://doi.org/10.1001/jama.2020.11932>

Twohey, M. (2020). Who Gets a Vaccine First? U.S. Considers Race in Coronavirus Plans. *The New York Times*. Retrieved July 27, 2020, from <https://www.nytimes.com/2020/07/09/us/coronavirus-vaccine.html>

U.S. Food and Drug Administration (FDA)(2020). *Development and Licensure of Vaccines to Prevent COVID-19*. Retrieved July 27, 2020, from <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/development-and-licensure-vaccines-prevent-covid-19>

Wamsley, L. (2020). Rick Bright, Former Top Vaccine Scientist, Files Whistleblower Complaint. *NPR*. Retrieved July 13, 2020, from <https://www.npr.org/sections/coronavirus-live-updates/2020/05/05/850960344/rick-bright-former-top-vaccine-scientist-files-whistleblower-complaint>

Zettler, Patricia J. (2017). Pharmaceutical Federalism. *Indiana Law Journal*, 92(3), 845-900.

Assuring Essential Medical Supplies During a Pandemic: Using Federal Law to Measure Need, Stimulate Production, and Coordinate Distribution

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SUMMARY. The global COVID-19 pandemic has temporarily increased demand for basic medical equipment and supplies, and disrupted global supply chains. Governments at all levels and the private sector have found themselves scrambling – and often competing – for the supplies they need. Federal law anticipates that emergencies can generate this kind of sudden demand for medical equipment. Federal agencies not only have ample legal authority to respond to shortages, but also the duty and the authority to prepare for emergencies by planning, supply-chain monitoring, investment and partnership with the private sector, and stockpiling. Perhaps the most important federal law for preventing and ameliorating shortages, and the primary focus of this Chapter, is the federal Defense Production Act (DPA). The DPA provides a menu of powers to stimulate production, strengthen supply chains, coordinate expertise, and resolve market failures. Although the shortfall in personal protective equipment and other basic medical equipment was anticipated by planners and demonstrated in simulation exercises, federal action to address the problem in the face of the pandemic have landed somewhere between failing and making matters worse. This Chapter recommends an independent commission be established to investigate and draw lessons from the federal public health response, but in the meantime points to two core, fixable problems related to law and administration: (1) the failure of Congress and successive administrations to provide sufficient resources to staff and maintain a vigorous infrastructure to prepare for surges in demand, and (2) the failure of the current administration to use its legal authority to lead, manage, rationalize and stimulate production and distribution of needed equipment.

Introduction

By the end of March 2020, health care entities were facing a severe shortage of personal protective equipment (PPE) and fearing a ventilator shortage. Health care workers – and patients and residents in nursing homes, prisons, and other congregate settings – experienced higher risks of infection, and the shortage of PPE led states to halt elective medical procedures. The shortage was the result of a sudden and substantial increase in global demand, as well as short-term interruption of exports as producing countries tried to redirect products to meet surging domestic demand. Similar shortages have continued to arise with respect to other supplies, including swabs, reagents, and pipettes.

The shortage of PPE and basic medical supplies was not a surprise. In August 2019, the federal government had concluded an exercise called “Crimson Contagion” simulating a novel respiratory virus emerging in China and quickly spreading across the globe. The exercise revealed sizable shortages in PPE. The leaked report concluded that “[t]he current medical countermeasure supply chain and production capacity cannot meet the demands imposed by nations during a global influenza pandemic” (HHS, 2019).

Crimson Contagion was a *response* story. It suggested that when a pandemic hit, state and federal officials would be uncertain of their powers and unable to act effectively in concert. But that dramatic

story is embedded in a *preparation* story, in which the confusion of the response stemmed from a set of failures to have staff, resources, innovations, and information ready for the predicted pandemic crisis. From the preparation point of view, the federal government was capable of foreseeing its dangerous incapacity; it just wasn't able to do anything about it.

The pandemic shortages are a market failure – supply is not keeping up with demand – but not a sign of a failing market: global production capacity is sufficient to meet usual demands. This defines the challenge for government: companies that invest in new production capacity to meet surge demand will be left with excess capacity when demand returns to normal. Companies, particularly U.S. companies, that enter or expand their place in the market will find themselves, when the pandemic is over, competing with Chinese and other foreign producers that are well-placed for many reasons to out-compete them. While it is perhaps comforting to imagine the U.S. government somehow nationalizing the production of medical equipment, in reality its task is to use its resources to manage the private sector within the confines of a global production system.

This Chapter looks through the lens of the law at the role of the federal government in meeting this challenge. The Department of Health and Human Services (HHS) has the authority under federal emergency law (the Stafford Act) and the Defense Production Act (DPA) to prepare for and manage shortages during medical emergencies that threaten national security (for a discussion of legal issues related to safety and quality of medical products and clearing regulatory hurdles to innovation, see Chapter 20). We first look at the issue of planning and preparation, with attention to the authority for supply chain monitoring and planning under emergency law and the DPA. We then look at the response – what happened and what, looking at legal authority and the public good, should have happened. We conclude with recommendations.

The Preparation Failure

Crimson Contagion was just the latest in a long chain of reports, assessments and plans raising the same red flags. The basic challenges to be overcome in preparing for the expected pandemic surge in demand for basic medical supplies were well known, and indeed were described in detail by Centers for Disease Control and Prevention preparedness staff (Patel et al., 2017):

- A market based on meeting demand just in time, with little capacity for meeting sudden large increases;
- A complex supply chain involving many producers and distributors, most based overseas;
- Lack of a system-wide monitoring of needs, consumption, production and distribution;
- Unpredictable distributor management of shortages (e.g., ad hoc rationing to customers);
- Effects of market uncertainty on manufacturer willingness to ramp up production; and
- Huge amounts of equipment required in a national emergency.

Given that the nature of the challenge was well known, true preparation would have entailed significant investment. Ideally, this

would have included building an up-to-date database of domestic manufacturers and distributors of all essential supplies, with an assessment of the short-term capacity of each manufacturer to increase production; an assessment of the likely national need; and a plan for allocating equipment to prevent crisis competition and take advantages of regional differences in the timing of peak demand. This information would have informed the inventory needs of a properly stocked Strategic National Stockpile (SNS), and efforts to support new technology and innovation that would increase readiness or help meet a surge. Preparation like this requires leadership and staff who are equipped to analyze and monitor the supply chain and to work creatively to develop solutions to the supply problems that can be implemented, or set in readiness, before the emergency arises.

There were no legal barriers to this work. Both the Stafford Act (the national emergency preparedness law) and the DPA contemplate ongoing preparation to include

assess[ing] on an ongoing basis the capability of the domestic industrial and technological base to satisfy requirements, ... specifically evaluating the availability of the most critical resource and production sources, including subcontractors and suppliers, materials, skilled labor, and professional and technical personnel; ... prepar[ing] in the event of a potential threat ... to take actions necessary to ensure the availability of adequate resources and production capability ... ; ...improv[ing] the efficiency and responsiveness of the domestic industrial base ...; and ... foster[ing] cooperation between the defense and commercial sectors for research and development and for acquisition of materials, services, components, and equipment to enhance industrial base efficiency and responsiveness. (Executive Order 13603, 2012).

The DPA has three titles that provided the president considerable authority to plan and respond quickly, without further congressional approval. Title I authorizes the government to jump to the front of the line in purchasing goods and empowers the president to allocate resources as “necessary or appropriate” (this “priorities” or “line-jumping” authority is commonly invoked, especially in defense contracting, but “allocations” power has not been invoked since the 1970s). Title III authorizes the government to assist private manufacturers, either by supporting existing supply chains or stimulating new technologies or modes of production. This allows measures like funding new machinery or making purchase commitments to ameliorate financial risks of ramping up production during a demand surge. Title III also authorizes the president to assess the industrial base, with power to get information by subpoena if necessary. Title VII authorities facilitate partnerships with the private sector, including in the form of voluntary agreements, to build capacity.

So how did HHS, the designated agency for this work in the case of health resources, do? Not well. Preparation was chronically neglected. In 2008, Congress directed the Government Accountability Office to examine whether key agencies had created guidance and regulations to implement the DPA. The resulting report noted that “the process for implementation is unclear and

could potentially cause delays in emergencies as agencies navigate the process” (GAO, 2008). When HHS finally issued a regulation for exercising its DPA supply chain management seven years later, it was “little more than cut-and-pasted from an antiquated, pre-existing rule the Department of Commerce first developed in 1984” (Brown, 2020). On the eve of the COVID-19 pandemic, the Crimson Contagion report found that officials “were not clear” on “the applicability or use” of the DPA in the face of these challenges (HHS, 2019).

Stockpiling was grossly inadequate in volume and range of supplies. The SNS, which like many public health services got a boost after 9/11, was neglected after contributing 85 million masks in the 2009 N1-H1 emergency. By March, 2020, it held only 12 million N-95 masks to help meet an estimated 3.5 billion mask demand (Whalen et al., 2020).

Finally, efforts to develop new technologies and capacities were conceived without sufficient ambition and implemented without necessary diligence. The Obama administration invested several million dollars to promote private sector development of a machine that could spit-out 1.5 million masks a day, but the project fell apart amid corporate take-overs, budget finger-pointing, and unrelated litigation. The Trump administration invested in a reusable N-95 mask, work on which is proceeding but will not likely be done in time to help with COVID-19. The total investment for both projects was about \$10 million, a small part of the reported \$1.5 billion budget of the HHS Biomedical Advanced Research and Development Authority (BARDA) overseeing the project (Swaine, 2020). There was no concerted effort to investigate other options, like truly “permanent” masks, or to address easily foreseeable shortages of ventilators, swabs, and reagents.

The Response Failure

The Crimson Contagion story became real life at the end of 2019. Having failed to prepare for the emergency, the first step for the administration in late December or early January should have been a rapid assessment of PPE, ventilators, and other supplies in public and private possession, backed as necessary by the powers conferred by Title III of the DPA. The second step should have been using Title VII of the DPA to convene a partnership of private and government sectors to organize a federal response to shortages that would have invoked authority to oversee allocation by the Federal Emergency Management Administration (FEMA) or another appropriate agency based on need. As inadequate supplies became apparent, the federal government should have issued huge purchase commitments, paying higher unit prices for earlier delivery and making long-term commitments to incentivize companies to assume the risks of jumping into the market or significantly increasing capacity. Federal coordination and procurement leadership would not have instantly solved the shortages, but it would have saved states money and effort by unifying purchasing in one buyer.

What happened instead was what Crimson Contagion predicted. By early January, the State Department’s epidemiologist had advised that a global pandemic was likely, the HHS had organized a task force, and the president was getting detailed briefings about the



Figure 21.1. *The New York Post* cover from March 26, 2020 (Bowden et al., 2020).

global spread of the disease – but action was lacking. At BARDA, future whistle-blower Rick Bright was already “alarmed about the scarcity of critical resources and supplies, including N95 masks, swabs, and syringes, and began clashing with HHS leaders as he pressed for them to take appropriate action to address these shortages” (Bright, 2020). HHS officials actually prevented the Food and Drug Administration commissioner in January from reaching out to industry to discuss increasing PPE production because, the *Wall Street Journal* reported, “such calls would alarm the industry and make the administration look unprepared.” Only at this point, with the fire lit, did the chief preparedness official at HHS order his staff to draw up plans to invoke the DPA.

Federal agencies only started to seriously respond to shortages in March, placing bulk orders for N95 masks and ventilators. On March 18, the president issued both an Executive Order “allowing” for the use of the DPA and a tweet that he did not plan to actually use his DPA power. Somewhere around this time, Jared Kushner created his own supply management team drawn from hedge funds and consulting firms, which, after its short run, would be criticized for its “delays, incompetence, confusion, and secrecy” in Congressional hearings. As even wealthy hospitals like New York’s Mount Sinai were leaving nurses to wear trash bags for gowns and purchase their own masks (see Figure 21.1), the president blamed state governors for failed procurement and dismissed an Inspector General report of pervasive shortages as “Another Fake Dossier!”

In late March, the president addressed concerns about the supply of ventilators, issuing a statement that directed HHS “to use any and all authority available under the [DPA] to require General

Motors to accept, perform, and prioritize Federal contracts for ventilators.” General Motors responded with a bewildered press release, noting that the president’s statement lacked specific requirements and that the company was already working as quickly as possible to ramp up production of ventilators. Although there was some loose tweeting about invoking the DPA to mandate specific companies to produce supplies, and even some media references to nationalization, there was no evidence – and quite a bit of skepticism – that direct government control would increase production given how little government understood about the capacity of different firms (Watney & Stapp, 2020). Pushing federal contracts to the head of the line was actually the easy part of the DPA compared to the job of understanding the amount and location of existing equipment. In late March, the senior Navy official leading FEMA’s supply chain efforts admitted that he was “blind to where all the product is” (Muller & Swan, 2020).

Spasmodic and confused federal behavior added to the burden of states trying to get supplies from the SNS or on the open market. States’ SNS requests were processed through an opaque (and quite possibly politically influenced) process. FEMA and HHS publicly announced different prioritization schemes, and in practice allocations varied tremendously. Florida received all the masks it requested in March; other states received a fraction of their requests (Table 21.1).

State procurement on the open market devolved into bitter competition between individual states and the federal government. Predictably, scarcity and competition increased prices for PPE across the board. Masks that once sold for \$0.85 were suddenly \$7. Then FEMA stepped in, invoking DPA priority to supersede state and private orders, and in at least one case seizing three million N95 masks on their way to Maryland. The governor of Kentucky voiced the general state lament: “The federal government says ‘States, you need to go find your supply chain,’ and then the federal government ends up buying from that supply chain.” In the face of federal coordination and supply failure, many states began to cooperate and even share equipment in formal and informal ways, like the purchasing consortium set up in New York and six other Northeast states.

The final federal initiative in the story so far was to add prevarication and insult to injury. In early April, presidential tweets blamed governors for supply shortages noting that “Some have insatiable appetites & are never satisfied (politics?).” The White House then moved to redefine the whole idea of the SNS,

with Jared Kushner proclaiming that the SNS is “supposed to be our stockpile. It’s not supposed to be states’ stockpiles that they then use.” The next day, this mission shrink was formalized by changing the public definition of the SNS, from a resource that “ensures that the right medicines and supplies get to those who need them most during an emergency” to a “short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available.”

Conclusion

The DPA provides a flexible set of powers that enables the executive branch to assume responsibility to plan, instigate and strategically coordinate public-private collaboration as part of a national program to assure necessary health supplies to every state. The federal government can still bring to bear its human and economic resources to identify shortages and nudge suppliers to ramp up production with investment and purchase orders; it can coordinate the purchase and distribution of existing supplies to get material where it is most needed. Long-term purchasing and investment deals will ultimately yield a surplus of basic supplies that can be used to rebuild a truly adequate SNS.

The law allows this, but it does not ultimately mandate action. Emergency powers obviously raise a potential problem of over-reach, an executive exploiting crisis authority for improper ends. The federal response to COVID-19 shortages has been a surprising and tragic example of the opposite – executive underreach (Pozen & Scheppele, 2020). The federal government has failed miserably and must at once bear grave responsibility for the harm it has failed to prevent and for rebuilding its preparation and response capacities. Congress may need to consider reshaping emergency law to create more binding duties for the executive branch.

There is blame to share. States have been complicit in the long-term underfunding of public health infrastructure, including state stockpiles. Shortages of equipment also demonstrate some shameful attributes of a health care industry that only Rube Goldberg would call a system. Hospitals and health care organizations live in a market that provides little incentive for emergency risk-assessment and response – or even protecting their workers.

There are fundamental equity problems in this mess. Mount Sinai staff to the contrary notwithstanding, when a product costs more the haves get more of it than the have-nots. Richer hospitals and health systems, in wealthier states, will all things being equal get

Table 21.1. Requested and Received N-95 Masks

STATE (POPULATION)	REQUESTED	RECEIVED	PERCENTAGE RECEIVED
Florida (21 million)	180,000	180,000	100%
Oregon (4 million)	400,000	40,000	10%
New Jersey (9 million)	2,900,000	85,000	3%
New York City (8 million)	2,200,000	78,000	4%
Notes: All of the NYC masks received were marked expired (DePillis et al., 2020).			

more and better PPE than poor institutions. Urban will generally beat rural. And in the health care workforce, the doctors, nurses, and other care staff in medical centers will do better than people working in nursing homes and prison infirmaries and other institutional or home care functions. The have-nots in this story are lower paid and more likely to be people of color, yet they are as at-risk and as essential as the workers fortunate enough to get the PPE they need. All these problems and the deeper inequities they reflect are solvable, but not without effective collective action by and through a government that expresses our shared responsibility and solidarity. On top of everything else, the failure to properly prepare and respond is just one more way in which COVID-19 has demonstrated the fundamental moral and political challenges of the “social determinants of health” in the United States (Berwick, 2020). 🌞

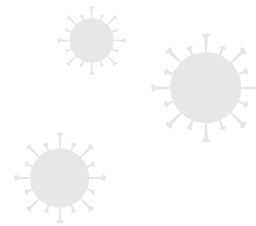
Recommendations for Action

Federal government:

- The president should empower and equip with the necessary resources competent career government staff to use federal emergency and DPA authority:
 - o Identify and assess the availability of all basic medical equipment required for COVID-19 response;
 - o Assess domestic and international production capacity and supply chains;
 - o Use investment and purchasing to incentivize manufacturers to add necessary capacity;
 - o Develop and implement a strategy for federal procurement and need-based distribution to states.
- Congress and the White House should jointly convene an independent commission of inquiry to conduct a thorough public investigation of the federal and state government preparation for and response to COVID-19.
- Congress should reaffirm the role of the SNS as the primary resource for the nation during emergency surges in demand, and institute a long-term funding plan for assuring supplies commensurate with predicted need.
- Congress should fund and HHS should properly implement and manage the long-term staff and infrastructure to monitor, track, and use the resources of BARDA to proactively address deficiencies in the supply chain for essential medical equipment.
- HHS should develop, with real attention, new regulations on emergency supply chain management including developing and implementing “stress tests” for supply chains for key products, and reorganize accordingly.

State governments:

- In the near term, as long as federal coordination lags, states should continue to formalize and extend interstate cooperation in procurement and sharing of resources.
- As revenues return to normal levels, and we see how federal government goes forward, states should make substantial investments in human resources, infrastructure, and procurement to create state stockpiles and ensure competent staff and leadership for emergency response.



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References

- Berwick, D. M. (2020). The Moral Determinants of Health. *Journal of the American Medical Association*. Retrieved July 21, 2020, from doi: 10.1001/jama.2020.11129
- Bowden, E., Campanile, C., & Golding, B. (2020). Worker At NYC Hospital Where Nurses Wear Trash Bags As Protection Dies From Coronavirus. *New York Post*. Retrieved July 21, 2020, from <https://nypost.com/2020/03/25/worker-at-nyc-hospital-where-nurses-wear-trash-bags-as-protection-dies-from-coronavirus/>
- Bright, R. (2020). Complaint of Prohibited Personnel Practice or Other Prohibited Activity. Retrieved July 21, 2020, from https://www.kmblegal.com/sites/default/files/NEW%20R.%20Bright%20OSC%20Complaint_Redacted.pdf
- Brown, J. (2020). The Defense Production Act and The Failure to Prepare for Catastrophic Incidents. Retrieved July 21, 2020, from <https://warontherocks.com/2020/04/the-defense-production-act-and-the-failure-to-prepare-for-catastrophic-incidents/>
- DePillis, L., Spies, M., Kaplan, J., Edwards, K., & Chen, C. (2020). Here's Why Florida Got All the Emergency Medical Supplies It Requested While Other States Did Not. *ProPublica*. Retrieved July 21, 2020, from <https://www.propublica.org/article/heres-why-florida-got-all-the-emergency-medical-supplies-it-requested-while-other-states-did-not>
- Executive Order 13603 (2012). National Defense Resources Preparedness. 77 Fed. Reg. 16651-16660. Retrieved July 21, 2020, from <https://www.govinfo.gov/content/pkg/FR-2012-03-22/pdf/2012-7019.pdf>
- U.S. Government Accountability Office (GAO)(2008). Defense Production Act: Agencies Lack Policies and Guidance for Use of Key Authorities. GAO-08-854. Retrieved July 29, 2020, from <https://www.gao.gov/assets/280/277418.pdf>
- Muller, J., & Swan, J. (2020). Fixing America's Broken Coronavirus Supply Chain. Retrieved July 5, 2020, from <https://www.axios.com/coronavirus-supply-chain-task-force-2b6be629-170c-4874-9991-7f8b3f6c5320.html>
- Patel, A., D'Alessandro, M. M., Ireland, K. J., Burel, W. G., Wencil, E. B., & Rasmussen, S. A. (2017). Personal Protective Equipment Supply Chain: Lessons Learned from Recent Public Health Emergency Responses. *Health Security*, 15(3), 244-252.
- Pozen, D. E., & Scheppele, K. L. (2020). Executive Underreach, in Pandemics and Otherwise. *American Journal of International Law*, 114 (forthcoming).
- Swaine, J. (2020). Federal government spent millions to ramp up mask readiness, but that isn't helping now. *The Washington Post*. Retrieved July 21, 2020, from https://www.washingtonpost.com/investigations/federal-government-spent-millions-to-ramp-up-mask-readiness-but-that-isnt-helping-now/2020/04/03/d62dda5c-74fa-11ea-a9bd-9f8b593300d0_story.html
- U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response (HHS)(2019). Crimson Contagion 2019 Functional Exercise Draft After-Action Report. Retrieved July 21, 2020 from the *New York Times*, <https://int.nyt.com/data/documenthelper/6824-2019-10-key-findings-and-after/05bd797500ea55be0724/optimized/full.pdf#page=1>
- Watney, C., & Stapp, A. (2020). Masks for All: Using Purchase Guarantees and Targeted Deregulation to Boost Production of Essential Medical Equipment. Retrieved July 21, 2020 from the Mercatus Center, https://www.mercatus.org/system/files/watney_and_stapp_-_policy_brief_-_covid_series_-_masks_for_all_-_v1.pdf
- Whalen, J., Helderman, R. S., & Hamburger, T. (2020, April 3). Inside America's Mask Crunch: A Slow Government Reaction and an Industry Wary of Liability. *Washington Post*. Retrieved July 21, 2020, from https://www.washingtonpost.com/politics/inside-americas-mask-crunch-a-slow-government-reaction-and-an-industry-wary-of-liability/2020/04/02/b3155e2a-6f85-11ea-aa80-c2470c6b2034_story.html

Allocation of Scarce Medical Resources and Crisis Standards of Care

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SUMMARY. Potential shortages of medical resources and services related to COVID-19 present government officials and emergency planners with difficult choices. If resources become too scarce, health care professionals and institutions may need to implement triage protocols adopting crisis standards of care. COVID-19 patient surges tested the health care system in March and April 2020, and highlighted the need to prepare to accommodate larger patient capacity in the near future. As a primary consideration, governments and health care institutions should utilize existing powers and resources to avoid shortages and mitigate their severity. If shortages do occur, most states have begun to develop crisis standards of care protocols to assist in making decisions about allocating scarce resources. These protocols attempt to maximize the number of lives saved. Many protocols give priority access to health care and other essential workers. These protocols should be structured to facilitate fair and equitable access, although several have been found to be inconsistent with federal antidiscrimination law. Legal issues that may arise in this context include liability for health care professionals and institutions who decide to not allocate resources to patients who later suffer harm, and civil rights concerns over discrimination arising from the protocols or their implementation. Liability shields have been put in place by many states to protect health care professionals from lawsuits based on allocation decisions. Federal and state officials should support efforts to clarify and incorporate protections into crisis standards of care plans that prioritize antidiscrimination, fairness, and equity in allocation decision making.

Introduction

This chapter addresses the legal and ethical issues that may arise when shortages of medical resources and services occur during the response to the COVID-19 pandemic. Health care facilities in the hardest hit areas have had to adapt their patient care practices to respond to the influx of COVID-19 patients. During the initial months of the COVID-19 outbreak, many U.S. hospitals faced shortages of key resources such as ventilators, beds, medications, and personal protective equipment (PPE), and had to consider contingency plans for allocating these scarce resources (HHS, 2020). These shortages have the potential to lead to some of the most gut-wrenching decisions a health care professional would ever have to make: how to decide who gets a resource when there is not enough of it to provide to everyone who needs it?

New York City hospitals were stretched nearly to the breaking point in April 2020, and only avoided enacting triage protocols through significant systemic adaptations (unprecedented coordination of patient loads and supplies between hospitals,

adapting space and altering treatment protocols—including ventilator sharing—to expand capacity) and social solidarity (the unprecedented physical distancing efforts across the population that bent the curve of COVID-19 infections downward). However, it is difficult to determine how many people may have been deterred from seeking care out of concern about the protocols being used to allocate medical resources and whether this contributed to higher mortality rates. Moreover, many health care or other essential workers were exposed to COVID-19 due to PPE shortages and have experienced high rates of infection (Nguyen et al., 2020). As hospitals, EMS, long-term care facilities, and public health departments in more areas experienced spikes in COVID-19 cases, it is vital to have plans in place that clearly outline protocols for avoiding scarcity. If scarcity does occur, including limited supplies of newly-developed treatments and vaccines, scarce medical resources and services must be allocated consistent with legal and ethical responsibilities that protect the most vulnerable persons through fair and equitable prioritization.

Avoiding Scarcity

A number of factors cause resource shortages during emergencies like the COVID-19 crisis. These include: inadequate planning and investment in surge capacity by governments and health care facilities; slow or insufficient reaction to novel public health risks that allows the case rate to grow to an unmanageable level; a lack of government leadership to coordinate distribution and sharing of necessary resources to facilities in need; and underlying economic incentives and systemic shortcomings inherent to the cost-centric, redundancy-averse, for-profit health care system in the United States. Notwithstanding, ethicists and prudent policymakers agree that avoiding scarcity of medical resources and services is much preferred to later invoking triage protocols out of necessity. Consequently, there is a duty to plan for surge capacity in the health care and public health settings to avoid the need to make tough allocation decisions (Hick et al., 2020; Berlinger et al. 2020).

Increased demand for medical resources and services are predictable during an epidemic, which is why emergency preparedness plans explicitly encourage health care and public health institutions to plan for and invest in surge capacity and capability. Most of these plans envision expanded capacity in three areas: space, staff, and supplies (IOM, 2012). A surge in patients can overtake the physical space in a healthcare facility. Many hospitals faced with an influx of COVID-19 patients in April 2020 reorganized their facilities to provide more intensive care beds, set up staging areas to evaluate patients in tents outside their facilities, and postponed elective medical procedures. In addition, state officials used executive orders to set up ad hoc spaces for medical care in convention centers in New York City, Detroit, Houston, and elsewhere. Staff capacity can be bolstered by lengthening shifts and increasing patient counts, waiving regulatory limitations to expand scope of practice, and bringing in additional health care professionals from other, less-affected areas. State law can be used to waive practice and staffing restrictions and to grant licensure reciprocity for health care professionals from other states. Indeed, state emergency powers laws often explicitly grant authority to governors or state officials to take these steps, as does the Emergency Management Assistance Compact. Access to supplies—the materials, medications, and medical devices needed to provide safe and effective care—has posed the most significant challenge during the initial stages of the COVID-19 epidemic. Shortages of PPE placed both health care workers and patients at higher risk of infection, while concerns about insufficient access to ventilators and medications raised the possibility that triage schemes could be needed to fairly and effectively deploy these resources. New York, facing the largest surge of COVID-19 cases in April 2020, took the unprecedented step of implementing a centralized management structure for staff and supplies under the state department of health, which was effective in coordinating surge capacity and resource use.

Federal, state, and local governments have emergency response plans in place that consider the need to address scarce resources during a public health emergency. Federal law provides resources, infrastructure, and support to specifically incentivize such planning through the National Disaster Medical System and the

National Hospital Preparedness Program, among other programs. However, over the past decade, federal support for emergency preparedness in general, and crisis standards of care planning in particular, have been curtailed (Trust for America's Health, 2019). Resource reductions for public health emergency preparedness undermine the capacity of health care and public health systems to effectively respond to a pandemic threat like COVID-19. The federal government plays a vital role in funding programs to avoid resource scarcity due to its capacity to deficit spend, a luxury most states don't have.

The federal government possesses two additional tools for expanding capacity to meet medical needs during shortages. The Defense Production Act has been invoked during the COVID-19 response as a possible way to compel manufacturers to produce ventilators and PPE (see Chapter 23). The federal government also maintains the Strategic National Stockpile, which contains medications and medical equipment available for distribution to states. During the initial phase of the COVID-19 response, supplies—including N95 respirators, face masks, face shields, gowns, gloves, and ventilators—were distributed to state and local jurisdictions based on a population formula, but this approach was later modified to take the prevalence of COVID-19 infections and local need, as well as political considerations, into account. Widespread distribution of resources between March and May 2020, however, have left the SNS depleted, raising concerns about shortages in subsequent COVID-19 outbreaks and concerns about the reluctance of Trump administration officials to fully utilize appropriated resources. Finally, federal resources supported efforts to enhance capacity to treat patients by supporting alternative care sites in convention centers and military hospital ships. Although these overflow sites only saw limited use, this approach could be helpful in future stages of the epidemic.

State laws similarly grant authority to the governor or designated state officials to implement strategies to expand access to resources during a declared emergency, disaster, or public health emergency. While these provisions vary somewhat state-to-state, they generally provide state officials with great leeway to waive state law requirements that would limit efforts to procure additional supplies quickly, authorize alternative sites for providing medical care, or expand the public health or health care workforce.

Legal Responsibility for Allocating Scarce Medical Resources and Services Crisis Standards of Care

An essential legal and ethical consideration in addressing the allocation of scarce medical resource is how scarcity affects the standard of care in health care settings. The National Academy of Sciences (NAS) (then the Institute of Medicine) published a series of influential reports addressing this issue and articulating standards and guidance for crisis standards of care (IOM, 2009; IOM, 2012; IOM, 2013). Crisis standards of care apply to situations where “a substantial change in usual healthcare operations and the level of care it is possible to deliver” occurs (IOM, 2009). This guidance further notes:

This change in the level of care delivered is justified by specific circumstances and is formally declared by a state government, in recognition that crisis operations will be in effect for a sustained period. The formal declaration that crisis standards of care are in operation enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facility operations.

The NAS approach identifies fairness, duty to care, duty to steward resources, transparency, consistency, proportionality, and accountability as important ethical considerations in allocating scarce resources; outlines indicators and triggers for when surge capacity has reached crisis levels; and develops support tools to assist with triage decisions (IOM, 2009; IOM, 2012). At least 34 states have developed guidance to address allocation of scarce medical resources and/or crisis standards of care, and many of these guidance documents adopt the NAS approach. Most of these plans include protocols that seek to save the most people possible by prioritizing patients with the greatest likelihood of successful recovery from treatment; grant priority to essential health care workers; and promote fairness and equity by prohibiting prioritization based on race, gender, national origin, religious affiliation, citizenship, sexual orientation, ability to pay, or assessments of a person's social value.

Many jurisdictions have developed this nonbinding guidance, but few states have enacted statutory provisions granting state executive officials the legal authority to alter standards of care during a declared emergency. Rather, this authority can be implied as a component of broadly-worded state and local emergency declaration powers. State legislatures should enact statutory provisions outlining the process for imposing crisis standards of care, such as those found in Virginia law (Virginia Code, secs. 8.01-225.01, 8.01-225.02), to establish a clear process for when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority.

Liability for Allocation Decisions

Tort law recognizes that health care professionals and institutions must adhere to the applicable standard of care, i.e. the standard of care that a professional would follow under the same or similar circumstances. Allocation decisions made and the level of care provided in the face of pandemic-induced shortages thus will be subject to different expectations under tort law than similar clinical decisions made under ordinary circumstances. It will likely be difficult for a plaintiff to persuade a jury that a health care professional or institution that followed state crisis standards of care guidance to allocate medical resources should be held civilly liable for any harm suffered due to not being offered access to that scarce resource, provided that a declared emergency, disaster, or public health emergency is in place. The plaintiff may have a stronger liability claim for a decision that reallocated a resource—such as a ventilator—away from a person using it to another person with a more favorable prognosis (Cohen et al., 2020; Truog et al., 2020).

Consequently, some states have gone further and implemented statutory protections for triage and scarce resource allocation decisions during declared emergencies. Maryland law, for example, provides health care providers with strong civil and criminal immunity for triage decisions, including removal and reallocation of a ventilator “if the health care provider acts in good faith” during a state-declared emergency (Maryland Code, Public Safety, sec. 14-3A-06; Cohen et al., 2020). Likewise, Virginia law protects health care providers from civil liability and criminal penalties during a state or local emergency where “the provider was unable to provide the requisite health care [as a result of the] response to the relevant disaster” or when “the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency” (Virginia Code, secs. 8.01-225.01, 8.01-225.02).

COVID-19-specific liability shields for health care professionals—and in some cases health care facilities—have been adopted by executive order in over 20 states. Similarly, federal law grants liability protections for health care professionals providing COVID-19 treatments under the PREP Act and to volunteer health care professionals under the CARES Act and the Volunteer Protection Act (see Chapter 27).

Only a few states have specifically invoked crisis standards of care in executive orders protecting health care workers from liability for decisions about scarce resource allocation. For example, on June 29, 2020 the Arizona Department of Health Services formally authorized the state crisis standards of care, allowing hospitals to implement triage protocols if necessary. Virginia governor Ralph Northam issued Executive Order 60 on April 28, 2020, applying immunity from liability for health care providers for “insufficient availability of PPE, ventilators, or other drugs, blood products, supplies or equipment” and “implementation or execution of triage protocols or scarce resource allocation policies necessitated by healthcare provider declaration of crisis standards of care.”

Despite these orders, it does not seem that health care providers or institutions actually implemented crisis standards of care in either state. Indeed, at this time, it remains unclear whether shortages requiring triage decisions have occurred in any jurisdiction; if such decisions are made, litigation will inevitably follow. It is appropriate for state law to provide liability protection for health care professionals making difficult decisions brought on by resource scarcity beyond their control. It is less clear that health care institutions should be held harmless for their failure to plan for predictable shortages during a pandemic, but they will likely face shortages exceeding their ability to prepare. It remains an ethical imperative that health care professionals and institutions, as well as public health officials, adhere to ethical and practical guidance from crisis standards of care protocols that are designed to mitigate the spread and harm of COVID-19 and maintain fair and equitable distribution of scarce resources (Emanuel et al., 2020).

Civil Rights Protections and Scarce Resource Allocation

Civil rights protections have particular importance in the context of scarce resource allocation decisions to insure such decisions do not discriminate, and are fair and equitable. Differential access to care and inequities in health outcomes exist in the United States even under normal circumstances and these disparities are exacerbated during the COVID-19 pandemic, especially for low-income communities, older people, people with disabilities, and communities that are primarily Black, Indigenous, and People of Color. People in these communities often face higher rates of serious illness, which could have the effect of reducing their priority to access scarce resources under scarce resource allocation models that favor patients with the highest likelihood of successful treatment (Shaw, 2020). Antidiscrimination provisions in federal and state law provide essential legal protections against discrimination in the context of scarce resource allocation decisions for members of these communities.

Most state crisis standards of care guidelines prohibit prioritization of access to resources based on demographic factors and factors related to social standing. However, since age and disability status could affect clinical assessments of medical prognosis and survivability, allocation protocols vary in their consideration of these factors. Problematically, a number of states' crisis standards of care plans explicitly deprioritize people with disabilities in decisions allocating critical care by categorically excluding people with certain physical or intellectual disabilities from receiving scarce resources or implicitly discriminating by basing triage decisions on long-term survivability or assessments of the patient's quality of life (Bagenstos, 2020).

Recognizing the potential for discrimination under the existing protocols in some states, disability rights advocates asked the U.S. Dept. of Health and Human Services Office for Civil Rights (OCR) to evaluate whether crisis standard of care policies in several

states (Alabama, Connecticut, Delaware, Massachusetts, New York, Pennsylvania, Utah, Tennessee, and Washington) violated federal civil rights laws. OCR enforces the Rehabilitation Act of 1974, Title II of the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act, all of which protect people with disabilities from discrimination in the health care setting (Mello et al., 2020). To date, OCR has resolved complaints against Alabama, Pennsylvania, and Tennessee, and these states have changed their crisis standards of care plans to remove discriminatory policies.

OCR also issued guidance stating that "no person should be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth,' including judgments about a person's worth based on the presence or absence of disabilities or age." Michigan Governor Gretchen Whitmer adopted nearly identical language in Executive Order 2020-64, prohibiting discrimination based on disability status in resource allocation decisions in health care settings.

Thus it appears that prospective application of antidiscrimination law has already led to modifications to crisis standards of care protocols that make them more fair and equitable in some states. Other states should review their crisis standards of care plans to clarify necessary protections under federal and state antidiscrimination law. States also should pursue public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most effected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols. These approaches will ensure that patients receive the best possible care even when resources are limited while simultaneously protecting against discrimination and disparate treatment of individuals from historically-marginalized communities. 🌟

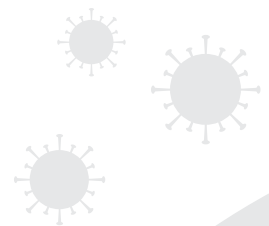
Recommendations for Action

Federal government:

- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund, and should expand support for the National Hospital Preparedness Program and the Strategic National Stockpile.
- HHS OCR should develop, expand, and update guidance for the allocation of scarce resource and crisis standards of care consistent with federal antidiscrimination laws.

State governments:

- State legislatures or executive agencies should develop and approve protocols for crisis standards of care and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies and clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19.
- State legislatures or executive agencies should pursue public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most effected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols.
- State legislatures should enact statutory provisions outlining the process for imposing crisis standards of care to establish a clear process for when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority.
- State legislatures should review their crisis standards of care protocols to clarify necessary protections under federal and state antidiscrimination law.
- States should assess, and if necessary, enact the requisite legal authority for executive branch officials to avoid medical resource and service scarcity through means such as resource stockpiling, alternate care sites, and health care workforce expansion.
- State legislatures should adopt liability shields for health care professionals and institutions related to decisions allocating scarce medical resources and services in the health care setting, provided that health care professionals and institutions follow state-adopted and implemented crisis standards of care protocols in good faith.
- State laws should prohibit medical allocation decision-making based on social stigma or stereotypes regarding age, color, criminal history, disability, ethnicity, familial status, gender identity, height, homelessness, immigration status, incarceration status, marital status, mental illness, national origin, poverty, race, religion, sex, sexual orientation, socio-economic status, substance abuse disorder, use of government resources, veteran status, or weight.



About the Author

Lance Gable, JD, MPH is an Associate Professor of Law at Wayne State University Law School. His research addresses the overlap among law, policy, ethics, health, and science. He has published journal articles on a diverse array of topics, including public health law, ethics and policy; international human rights; emergency preparedness; mental health; research ethics; and information privacy. He developed ethical guidelines for the allocation of scarce medical resources during public health emergencies for the state of Michigan and has worked with the World Health Organization and the Pan American Health Organization.

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References

- Bagenstos, S. (2020). Who Gets the Ventilator? Disability Discrimination in COVID-19 Medical-Rationing Protocols, *130 Yale L. Review Forum*.
- Berlinger, B., Wynia, M., Powell, T., Hester, D. M., Milliken, A., Fabi, R., ... Piper Jenks, N. (2020). Ethical Framework for Health Care Institutions Responding to Novel Coronavirus SARS-CoV-2 (COVID-19): Guidelines for Institutional Ethics Services Responding to COVID-19. Retrieved August 3, 2020, from <https://www.thehastingscenter.org/ethicalframeworkcovid19/>
- Cohen, I. G., Crespo, A. M., & White, D. B. (2020). Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19: Assessing the Risks and Identifying Needed Reforms, *323(19) JAMA* 1901-1902.
- Emanuel, E. J., Persad, G., Upshur, R., Thorne, B., Parker, M., Glickman, A., Zhang, C., Boyle, C., Smith, M., & Phillips, J. P. (2020). Fair Allocation of Scarce Medical Resources in the Time of COVID-19, *New England Journal of Medicine* 382, 2049-2055.
- Hick, J. L., Hanfling, D., Wynia, M. K., & Pavia, A. T. (2020). Duty to Plan: Health Care, Crisis Standards of Care, and Novel Coronavirus SARS-CoV-2. *NAM Perspectives*.
- Institute of Medicine (2009). Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report. Retrieved August 3, 2020, from <https://www.ncbi.nlm.nih.gov/books/NBK219958/>
- Institute of Medicine (2012). Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response. Retrieved August 3, 2020, from <https://pubmed.ncbi.nlm.nih.gov/24830057/>
- Institute of Medicine (2013). Crisis Standards of Care: A Toolkit for Indicators and Triggers. Washington, D.C.: The National Academies Press.
- Mello, M. M., Persad, G., & White, D. (2020). Respecting Disability Rights—Toward Improved Crisis Standards of Care, *New England Journal of Medicine* 383, e26.
- Nguyen, L. H., Drew, D. A., Joshi, A. D., Guo, C., Ma, W., Mehta, R. S., ... Chan, A. T. (2020). Risk of COVID-19 among frontline healthcare workers and the general community: a prospective cohort study. *National Institutes of Health*.
- Shaw, A. (2020). COVID-19: Racial Disparities and Crisis Standards of Care. Retrieved August 3, 2020, from <https://www.networkforph.org/resources/covid-19-racial-disparities-and-crisis-standards-of-care/>
- Truog, R. D., Mitchell, C., Daley, G. Q. (2020). The Toughest Triage—Allocating Ventilators in a Pandemic, *New England Journal of Medicine* 382, 1973-1975.
- Trust for America's Health (2019). Ready or Not: Protecting the Public's Health from Diseases, Disasters, and Bioterrorism. Retrieved August 3, 2020 from <https://www.tfah.org/report-details/ready-or-not-protecting-the-publics-health-from-diseases-disasters-and-bioterrorism-2019/>
- U.S. Department of Health and Human Services, Office of Inspector General (2020). Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey. Retrieved August 3, 2020 from <https://oig.hhs.gov/oei/reports/oei-06-20-00300.pdf>

The background consists of a teal upper half and a red lower half, separated by a horizontal line. A large, light teal circle is positioned on the left side, overlapping both the teal and red areas. The text is located within the teal portion of the circle.

PART 5

Protecting Workers and Families

Summary of Recommendations for Protecting Workers and Families

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Protecting Workers and Families* address food security, housing, and worker safety. Recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal, state, and local guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic

Action at the Federal Level

- To reduce COVID-19 transmission and cushion the economic impact of COVID-19 on workers and their families, Congress should
 - o Strengthen, extend for a longer period of time, and eliminate the employer exemptions to paid leave in the Families First Coronavirus Response Act (FFCRA) and provide comprehensive emergency paid sick leave and paid family and medical leave, fully funded by the federal government (Terman, Protecting Workers; Silverman, Contact Tracing; Gable, Mass Movement; see also Krueger, Mental Health)
 - o Enhance FFCRA enforcement by
 - Allocating more funding to the Department of Labor (DOL) for FFCRA enforcement and outreach
 - Funding legal aid and community organizations to engage in outreach and enforcement
 - Requiring DOL to advise workers and employers to consult state and local laws that go above and beyond federal law to increase awareness of and compliance with all applicable leave protections
 - Requiring employers claiming exemptions under FFCRA to report and justify the exemptions to DOL (Terman, Protecting Workers; see also Krueger, Mental Health)
 - o Extend unemployment benefits, including Pandemic Unemployment Compensation and the Paycheck Protection Program, for the duration of the pandemic (Terman, Protecting Workers; Krueger, Mental Health)
 - o Create a permanent paid family and medical leave social insurance program (Terman, Protecting Workers)
 - o Enact a national paid sick leave law, not limited by worker status or employer size, with retaliation protection (Yearby, Protecting Workers; Terman, Protecting Workers)
 - o Revise unemployment insurance rules
 - To eliminate penalties on workers with both wages and self-employment earnings
 - Clarify that workers have the right to refuse unsafe work and remain eligible for unemployment benefits
 - Reform the Pandemic Unemployment Assistance program to allow waivers of overpayments (Terman, Protecting Workers)
- o Expand access to the workshare program (Terman, Protecting Workers)
- To make workplaces safer from COVID-19 and future pandemics,
 - o Congress should enact law giving OSHA authority to address food production speeds to enable social distancing (Yearby, Protecting Workers)
 - o OSHA should
 - Adopt an emergency temporary standard based on the proposed airborne infectious disease rule
 - Publish a final rule based on the proposed airborne infectious disease rule that includes the authority to regulate food production speeds
 - Make complaint data publicly available and disaggregate by industry to determine businesses that are hotspots for COVID-19
 - Conduct in-person inspections of business that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities
 - Mandate testing of workers employed at businesses that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities
 - Work with CDC to Track COVID-19 infections and deaths by occupation to determine what workers are most impacted by COVID-19
 - Mandate testing of all workers after identification of

an infected worker to prevent the spread of COVID-19 at workplaces (Yearby, Protecting Workers; see also Sinha, PPE)

- Congress should not pass any legislation shielding businesses from liability for failing to protect the health of customers and employees (Haddow et al., Preemption; Terry, Liability Shields)
 - o Any limited immunity granted at the federal level (for example, to protect vaccine manufacturers and prescribers) should be carefully calibrated and include a federal compensation scheme (Terry, Liability Shields)
 - o In any laws enacted to shield businesses from liability, include worker economic and safety protections including, but not limited to hazard pay, death benefits, workers' compensation for COVID-19 infections, mandatory infectious disease protections, and significant increased funding and authority for enforcement of worker health and safety laws (Yearby, Protecting Workers)
- Congress should amend the Federal Arbitration Act (FAA) to allow state and local laws restricting or prohibiting mandatory arbitration between employers/employees and businesses/ consumers (Haddow et al., Preemption)
- To promote affordable housing and keep people in their homes during and after the COVID-19 pandemic, Congress should
 - o Amend the Affordable Housing Credit Improvement Act of 2019 to increase the tax credit allocations by 50% in order to increase the supply of affordable housing
 - o Amend Section 8 of the United State Housing Act of 1937 and use its appropriations powers to:
 - Increase the income eligibility limits to 200% of the Federal Poverty Level
 - Increase the funding levels for Housing Choice Vouchers by at least 300%
 - Allow non-violent, formerly incarcerated individuals to be eligible for Housing Choice Vouchers and prohibit state and local government from increasing the duration of any bans or otherwise enact more restrictive laws than federal law
 - o Amend the CARES Act to
 - Extend the time limit on eviction and foreclosure moratorium for homeowners with FHA-insured single-family mortgages
 - Provide loan forgiveness for three months for owners of multifamily properties with federally-backed loans
 - Allow for the allocated \$4 billion for Homeless Assistant Grants and Emergency Solution Grants to be used for permanent, supportive housing for people experiencing homelessness, and increase the availability and amount of these funds beyond September 2022 (Anderson, Housing)
- To enhance food security,

- o Congress should
 - Temporarily increase the maximum value of the SNAP allotment by 15% or by linking benefit calculations to the Low-Cost Food plan, with duration of this allotment increase linked to an economic recovery metric
 - Increase the minimum value of a SNAP allotment from \$16 to \$30
 - Link the duration of the temporary Able-Bodied Adult Without Dependents Requirement (ABAWD) waiver to the nation's economic recovery, rather than the termination of the public health emergency declaration
 - Repeal legislation that bans individuals with felony drug convictions from participating in the SNAP program (21 USC § 862a)
 - Pass legislation that makes the online SNAP pilot a permanent program
 - Pass legislation requiring food retailers participating in the online SNAP program to offer free delivery under certain conditions
- o The Department of Agriculture should
 - Rescind recently promulgated regulations (84 Fed Reg 66,782) that restrict ABAWD access to SNAP
 - Rescind regulations (84 Fed Reg 35,570) that decrease access to nutrition programs by restricting SNAP categorical eligibility
 - Work with states and food retailers to expand the online SNAP pilot to all 50 states (Swinburne, Food Insecurity)

Action at the State Level

- To protect workers, their families and communities from COVID-19 and future pandemics
 - o Governors, through executive orders, and/or legislatures, through amending extant housing, utilities, and employment laws, should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to quarantine and/or isolation or other COVID-19-related events (Silverman, Contact Tracing; Gable, Mass Movement)
 - o Legislators should enact a statewide paid sick leave requirement, not limited by worker status or employer size, with retaliation protection for those not covered by a national law
 - o OSH agencies in states with approved plans should
 - Adopt an emergency temporary standard based on the proposed airborne infectious disease rule
 - Publish a final rule based on the proposed airborne infectious disease rule that includes the authority to regulate food production speeds
 - Make complaint data publicly available and disaggregate by industry to determine businesses that are hotspots for COVID-19

- Conduct in-person inspections of business that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities
- Mandate testing of workers employed at businesses that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities (Yearby, Protecting; see also Sinha, PPE)
- Legislatures should not pass any legislation shielding businesses from liability for failing to protect the health of customers and employees (Terry, Liability Shields)
 - o In any laws and regulations enacted to shield businesses from liability, include worker economic and safety protections including, but not limited to hazard pay, death benefits, workers' compensation for COVID-19 infections, mandatory infectious disease protections, and significant increased funding and authority for enforcement of worker health and safety laws (Yearby, Protecting Workers)
 - o In adjudicating claims of immunity, courts should
 - Interpret emergency COVID-19 shields narrowly to avoid creating unjustifiably broad immunities, recognize [1][2] they were designed to protect front-line workers during a limited period of unprecedented demand, stress, and shortness of supplies
 - Carefully scrutinize the constitutionality of shields and not show the same deference to legislative action given to malpractice reform
 - Void the exculpatory clauses being inserted into theme park and other contracts (Terry, Liability Shields)
- To reduce evictions and increase safe and affordable housing options, state legislatures should
 - o Appropriate funds and enact laws to provide rental assistance grants to low-income renters and to landlords to reduce evictions and rehabilitate structures with environmental hazards
 - o Establish or clarify the rule that evictions are limited to where housing owners can demonstrate good cause
 - Good cause should be generally limited to a) incidents that threatened the life or well-being of any tenant in the building, or b) a violent crime
 - During and for six months after the COVID-19 emergency, good cause should exclude non-payment of rent (Anderson, Housing)
- Courts should interpret emergency orders or declarations regarding evictions broadly, to freeze evictions in all forms and at all stages, including filings and notices (Anderson, Housing)
- To enhance food security in the absence of federal action, state legislatures should
 - o Completely opt out of the SNAP ban on individuals with felony drug convictions
 - o Increase the minimum value of SNAP allotment within the state and allocate the necessary state funds to supplement the federal benefit (Swinburne, Food Security)
- To address social and behavioral factors that increase the risk of mental illness, legislators should
 - o Enact and implement laws to limit access to guns among those who are shown to pose a danger to themselves or others (extreme risk protection orders or red flag laws)
 - o Identify and provide funding to fill gaps in practical assistance at the federal level, such as diaper need, which may be addressed through grants and assistance to diaper banks, assistance to families receiving work support, and exemptions from state sales tax
 - o Make free, public pre-kindergarten available to all children in the state, and establish guidelines regarding social and emotional learning
 - o Increase the minimum wage (Krueger, Mental Health)

Action at the Local Level

- Government officials should authorize the use of Homeless Assistance Grant funds received from states via the CARES Act for safe alternative, longer-term housing for people experiencing homelessness that includes supportive services and sanitation measures (Anderson, Housing)
- Local government, through Emergency Orders and/or amending extant housing, utilities, and employment laws, should extend protections against eviction, mortgage foreclosure, utility shut off, discrimination, and employment loss due to quarantine and/or isolation or other COVID-19-related events (Silverman, Contact Tracing; Gable, Mass Movement)
- To prevent public housing tenants from experiencing homelessness,
 - o PHAs by rule and/or local governments by ordinance should:
 - Stop the initiation or completion of evictions for non-violent or emergency reasons until after state or local emergencies are over
 - Extend the repayment period to a minimum of six months after the end of the moratorium
 - Stop the collection of any late fees during the suggested extended repayment period, even if such fees were charged prior to the beginning of the moratorium
 - Eliminate any restrictions on individuals who were evicted from private housing from the Housing Choice Voucher program
 - o PHAs should exercise their authority to cease enforcement of any minimum rent during the pandemic and for a period for at least six months after (Anderson, Housing)

A Pandemic Meets a Housing Crisis

Courtney Lauren Anderson, JD, LLM, Georgia State University College of Law

SUMMARY. Housing instability in the United States has been exacerbating health disparities and causing worse health outcomes for low-income individuals and people of color well before the COVID-19 pandemic. Individuals with low- or no-income experience intermittent utility connection, are more likely to be evicted, and spend a higher percentage of their income on housing costs. There is an insufficient supply of safe, affordable housing. As a result, people are homeless, live in substandard conditions, and experience economic insecurity. COVID-19 increased the number of families afflicted with housing instability and prompted an unprecedented government response to this issue. Certain legal constraints that perpetuated a system of discrimination were rapidly suspended or amended when middle- and upper-class people found themselves struggling with housing and utility payments, income insecurity, and other stressors of the pandemic. Historically, these burdens were concentrated in the low-income population, with an emphasis on people of color. Therefore, it follows that the grace and concern extended during the pandemic still reflects bias against socioeconomically disadvantaged groups and empathy towards higher-income people. In many instances, laws that are equally applied to all individuals widened the gap between people at different places on the socioeconomic continuum. People facing additional hardships need extended grace periods for rent and utility payments. The short-term solutions instituted during COVID-19 did not address the digital gap, the needs of formerly incarcerated people, or the reality that low-income groups will inevitably experience the same unstable situations they were in prior to the pandemic. Individuals who are more likely to be affected by housing instability belong to socioeconomic groups that are being disproportionately and adversely affected by COVID-19. These compounding demographic factors complicate the legal response to housing problems. Recommendations for mitigating the negative effects of policies and regulations focus on addressing issues omitted from the COVID-19 housing laws, expanding the laws that were put into place, and targeting the underlying causes of housing instability in order to proactively prevent such instability.

Introduction

Interrelated and systemic factors of race, income, and health create unique housing challenges for underserved communities that have persisted for decades. The 2018 poverty rate in the United States was just under 12%, with approximately 38 million peopling living at or below the poverty line. The rates of poverty for Black people (20.8%) and for Latino people (17.6%) are disproportionately high (Poverty USA, 2019). Housing is considered affordable if housing costs do not exceed 30% of household income. Over 50% of renters in the United States exceed this budget (Sisson et al., 2020). At \$1017 per month, the average fair market rent for a one-bedroom home is far above the \$655 a family of four at the federal poverty line of \$26,200 could afford. With just 37 rental homes available for every 100 renters with incomes at or below the poverty level, affordable housing is in short supply. This affordable housing shortage exacerbates racial housing disparities, because Black and

Latino Americans are much more likely than whites to fall into the extremely low-income category.

Families sacrifice purchasing other necessities when a large percentage of income is dedicated to housing. Low-income individuals often have to decide between paying the rent or mortgage, or face eviction, and buying medicine, healthy food, or other items that would prevent negative health outcomes. One study in 2015 determined that people experiencing cost burdens for housing are placed in this position at higher rates than those who are not. These cost-burdened households spent 53% less on non-housing necessities compared to their counterparts (Owens-Young, 2019).

Health disparities also stem from the type of housing that is available to people who live in poverty. Housing available to families at or below the poverty line often has structural problems,

including asthma-causing allergens and lead paint (Owens-Young, 2019). Substandard housing becomes the de facto “affordable housing,” because it is the only housing within the price range for low-income people.

Housing Laws and Policies in Response to COVID-19

In March 2020, Congress passed the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which addresses several housing issues stemming from the coronavirus outbreak. A summary of the pertinent clauses follows, together with state and local laws that mitigate housing insecurity due to the pandemic. The beneficiaries of the CARES Act are people who rent or own homes financed with Department of Housing and Urban Development (HUD) or Federal Housing Administration (FHA) funds, or that are secured by a Freddie Mac or Fannie Mae mortgage, all of which are defined as “Federally Impacted Properties” (Coronavirus Aid, Relief and Economic Security Act, 2020). Although a large percentage of financing for public housing is allocated by the federal government to the states and comes with broad guidelines, local public housing authorities (PHAs) are responsible for the use of the funds, public housing operations, and the general administration of housing programs. States and local governments also have the ability to increase housing stability during the pandemic by expanding and extending protections put in place by the CARES Act to all citizens. This can mean increasing the time frame for eviction protections, adding other prohibitions on tenant removal, or any other type of assistance that would allow more people to stay in their homes. This Section categorizes and critiques laws at all levels of government. In doing so, it illuminates the socioeconomic disparities created by laws in the midst of COVID-19, which adversely affects Black, brown and low-income people at higher rates.

Public Housing

HUD allocated \$1.25 billion for tenant-based rental assistance to help public housing agencies maintain normal operations. The CARES Act allocates an additional \$685 million for public housing operations through the end of 2020. The majority of low-income housing units are multifamily structures. The high concentration of people in these buildings make social distancing complicated. Individuals who reside in public housing are also subject to ongoing eligibility requirements which require interactions, putting the staff and residents in these accommodations at greater risk of infection. While the money is helpful, the distribution of funds is to avoid terminating rental assistance for these families or to “support and maintain the health and safety of assisted households...” It is outside the scope of the Act and allocation guidelines to use the funds for updating the structure of the buildings or eradicating the barriers to access public housing that certain populations face. As a result, housing remains a factor that can cause the pandemic to disproportionately impact low-income people and communities of color.

Rent Abatement and Rental Assistance

Most states and the CARES Act do not prevent landlords from increasing rents during the COVID-19 emergency. Governor Jay Inslee of Washington issued an executive order prohibiting rent

raises during the emergency period, but Washington is only one of two states to do so. Only nine states prevented late fees from being charged and four states mandate a grace period for rent. Cities also have the ability to provide financial aid to tenants. Indianapolis, IN approved \$15 million for rental assistance. Overall, state and federal laws simply do not provide long-term housing solutions for rent and housing stabilization.

Mortgage Forbearance

The federal government enacted a forbearance of residential mortgage loan payments for multifamily properties with federally backed loans through the CARES Act. An initial forbearance is granted for up to 180 days for those experiencing coronavirus-related hardships, with an optional 180-day extension. Fees and penalties may not be assessed during the extension. Forbearance is available through the earlier of December 31, 2020 or the termination of the national emergency. This provision prohibits eviction from such properties until August 31, 2020 (Coronavirus Aid, Relief and Economic Security Act § 4023, 2020). States can expand this protection, as New York did, by legislating mortgage forbearance to people with mortgage from state-regulated financial institutions.

Eviction Moratoria

The CARES Act provides a moratorium on eviction for residents of Federally Impacted Properties until August 31, 2020. This prohibits the recovery of housing possession from the tenant due to nonpayment of rent, including late fees (Coronavirus Aid, Relief and Economic Security Act § 4024, 2020). Eviction proceedings initiated prior to March 27, 2020 are not covered by this federal law, so some tenants must rely on state and local laws to keep their homes. Many states have refused to implement statewide eviction and housing stability orders, which means landlords may charge late fees for past due rental payment, utilities may be disconnected, there may be utility reconnection fees, and landlords are able to increase rent even during the eviction moratorium (Eviction Lab, 2020).

Twenty-eight states have restricted some part of the eviction process during the state of emergency. However, some of these states only prohibit select phases of eviction. For example, Maryland courts suspended hearings, judgments of possession, and have extended deadlines for tenants to respond. However, Maryland is still initiating evictions by sending notices to quit and continuing to file evictions against all tenants, even those with a COVID-19 hardship (Eviction Lab, 2020). Connecticut’s executive order is one of the more tenant-friendly ones, generally prohibiting eviction filings, except in cases of emergencies. Connecticut’s order extends to all stages of eviction including notices to quit, filings, hearings, rulings and executions. This is significant because if a state prohibits execution of evictions, but still permits filings, the tenant receives a notice of an impending eviction which can disrupt the tenant’s housing status and well-being.

Of the 28 states that have stayed some part of the eviction process during the state’s emergency declaration, only eight of these states opted to extend the eviction moratorium past the emergency

declaration expiration (Eviction Lab, 2020). The extension dates vary, with some giving a specific date, such as Massachusetts's date of October 17, 2020, and others depending on when the state of emergency ends (Eviction Lab, 2020). Vermont is one example of an eviction moratorium that terminates one month after the state of emergency ends. Thirty days is insufficient time to expect people making low or no income to pay rental expenses, in full (Eviction Lab, 2020). Also, only 18 states issued a foreclosure moratorium, leaving many homeowners subject to removal. Eviction moratoria, even if extended, only delay evictions for people who are experiencing COVID-19-related economic distress (Eviction Lab, 2020).

Adding to the complexity is the fact that eviction law and process is often governed by rules at the local or judicial district level. In Georgia, for example, the court process depends on which one of the 159 counties is processing the claim (Sudeall et al., 2020). Although there is a statewide suspension of eviction hearings, there is variation across counties on issuing judgments, whether the courts are open, and which ones have moved their operations online. Many counties have continued to accept eviction filings.

Utilities and Internet

Twenty-seven states have prohibited utility companies from disconnecting services during the state of emergency, but only seven states provided utility reconnection at no charge to the resident. Requiring tenants to pay hundreds of dollars will be a barrier to utility access to several low-income residents. Similar to many of the housing laws mentioned, tenants remain at risk of losing access to electricity and water if the shutoff was ordered prior to the pandemic. This creates obvious complications to safely sheltering in place. Also, eligible individuals may receive a loan of up to \$10,000 to pay for utilities through the Paycheck Protection Program. (Coronavirus Aid, Relief and Economic Security Act § 1102, 2020). Applying to this program, together with many other economic and educational necessities, is reliant upon internet access, which is not provided for in the CARES Act and which low-income residents are less likely to have, particularly in an economic crisis. Residents who receive temporary relief from utilities may be exempt from termination of their gas, electric and water services. The lack of internet access, even temporarily, deepens the digital divide at a time when children rely on the web for education, jobs have moved online, and pertinent information about how to stay safe during COVID-19 is primarily disseminated on the internet. It is also important that many counties have moved court hearings online, so without reliable internet citizens' due process is interrupted. Though some providers allowed for uninterrupted internet service in residences, this grace expired, for the most part, either at the end of the school year or within two months from the end of the school year. (See Chapter 30, Broadband Access)

Now is the time for localities to pass legislation creating efficient access to internet in emergencies so that bureaucracy does not bar residents from receiving the tools they need for survival.

People Experiencing Homelessness

Funds were appropriated through the CARES Act to help prevent a coronavirus outbreak amount people who are unsheltered and households earning less than 50% of area median income. Four billion dollars for Homeless Assistance grants will be available until September 30, 2022. The funds may be used for temporary emergency shelters, staff costs, rapid rehousing, rental deposit assistance and related housing assistance. Local agencies can provide guidelines for using those funds to increase housing. For example, Washoe County, Nevada partnered with a private company to create 375 beds for unhoused people, and also provided them with bathrooms and COVID-19 screenings (Washoe County, 2020).

Health Disparities and Housing

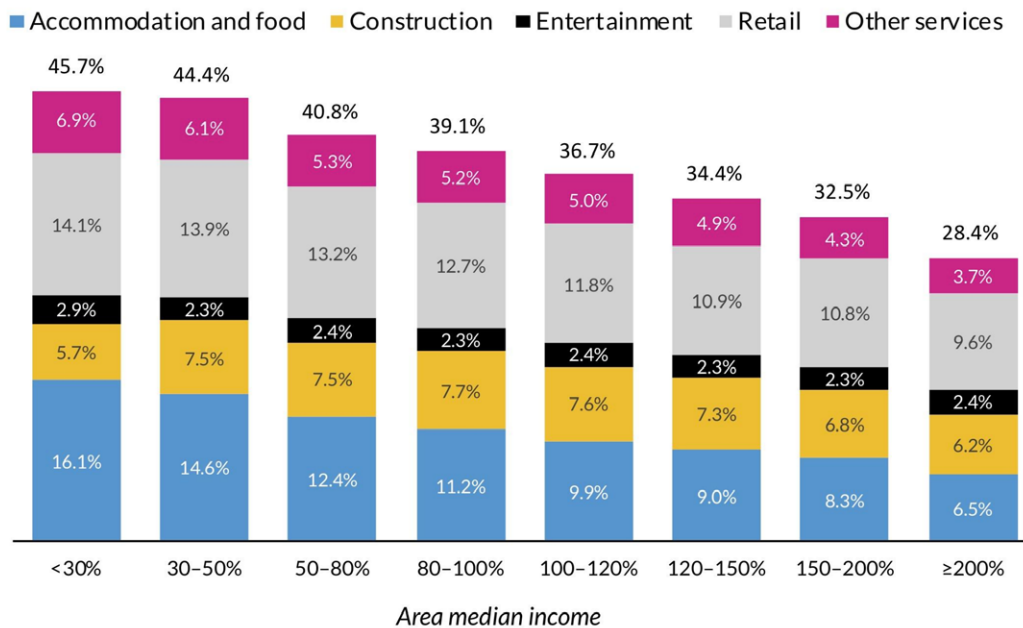
Deficiencies in the housing-related provisions of federal, state and local COVID-19 legal responses are evident, and the short-term nature of the laws that were passed illustrates the self-help framework typically applied in anti-poverty and housing policy. However, supporting individual resilience is not an effective way to approach systemic housing inequities. Upon the expiration of these laws, it is foreseeable that low-income individuals will be in the same, or worse, position than they were prior to the pandemic. These individuals face challenges other than housing, and their race and socioeconomic status puts them at greater risk for health inequities.

Low-income workers, who are more at risk for housing instability, have occupations that expose them to COVID-19 at higher rates, and are less likely to receive adequate health insurance (Garfield et al., 2020). The majority of low-income renters are minorities. Minorities have suffered from COVID-19 at disproportionately high rates and have experienced serious symptoms of the virus. Non-Hispanic black people, Hispanics and Latinos, and American Indians/Alaska Natives, experience higher rates of hospitalization and death from COVID-19 than non-Hispanic white people (Center for Disease Control, 2020).

Housing insecurity compounds the disparate health effects of COVID-19. There is high demand for rental assistance funds, and upon their depletion, low-income workers will, again, struggle to find the funds to pay for housing. Without loan forgiveness, or an established fund to cure mortgage defaults, low-income homeowners will simply owe more money at a later date, thereby postponing rather than preventing economic and housing instability. All of these factors increase the likelihood of eviction, which, in turn, worsens health outcomes. Eviction is linked to a myriad of negative physical and mental health outcomes, including stress-related illnesses such as depression and suicidal thoughts. Notably, respiratory diseases and increased mortality are more prevalent among individuals experiencing eviction (Benfer, 2020).

Forbearances for Federally Impacted Property are helpful, but leave many people out. States have the ability to direct state-regulated servicers and lenders to provide long-term loan modifications that

Share of workers in vulnerable industries, by income for entire labor force



Source: Urban Institute calculations from the 2018 American Community Survey.

URBAN INSTITUTE

Note: We grouped household income relative to the area median income and looked at all individuals within those households. For non-metropolitan statistical areas (MSAs), median household income is calculated by using the population within the state who are not living in MSAs.

Figure 1: Low-Income Renters Are More Likely to Work in the Five Industries Most Vulnerable to COVID-19 (Urban Institute, 2020).

would include payment reductions, forgiveness and longer grace periods – but have generally not done so. Nor have governments at any level addressed two key risks disproportionately faced by low income people and communities of color: dangerous physical housing conditions, and housing barriers for people leaving prison.

Low-income housing often contains health hazards that can cause “asthma, respiratory infections, lead poisoning, learning disabilities, behavioral and mental health problems, injuries, long-term brain damage, cancer, and other harmful conditions” (Benfer, 2015). These illnesses aggravate COVID-19 symptoms and eliminating mold and allergens from homes at no cost to the residents would reduce health implications and costs of these elements. However, the dearth of structural deficiency inclusion in local, state and federal housing laws addressing the pandemic illustrates the lack of attention to long-term, preventive measures in these regulations. The CARES Act is silent on this issue, and few states have acted. Setting an example, the Clifton County Home Improvement Project in New Jersey received federal funds to assist homeowners with repairing housing code violations, and other counties should use resources to do the same (Clifton County, 2020).

Incarcerated and formerly incarcerated individuals are disadvantaged in a number of ways, including being excluded or discriminated against with respect to public housing assistance

and other housing options. As a result, formerly incarcerated people experience homelessness at much higher rates, especially in the time directly after they are released. Although people in prisons and jails were being released to home confinement in order to slow the spread of the virus, many people had no home to go to. While lack of housing options has always afflicted this community, the health and economic implications of not being able to find housing are worsened during the pandemic. Black men and women who were incarcerated have higher rates of unsheltered homelessness compared to their counterparts (Couloute, 2018). Without laws during a pandemic that specifically provide for housing options for this population, the ability for early release and home confinement provisions to reduce negative health outcomes is severely stymied.

Recommendations for Action

Federal government:

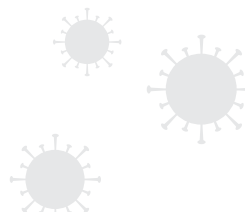
- Congress should amend the Affordable Housing Credit Improvement Act of 2019 to increase the tax credit allocations by 50% in order increase the supply of affordable housing.
- Congress should amend Section 8 of the United States Housing Act of 1937 and use its appropriations powers to:
 - o Increase the income eligibility limits to 200% of the Federal Poverty Level;
 - o Increase the funding levels for Housing Choice Vouchers by at least 300%;
 - o Allow non-violent, formerly incarcerated individuals to be eligible for Housing Choice Vouchers and prohibit states and local government from increasing the duration of any bans or otherwise enact more restrictive laws than federal law.
- Congress should amend the CARES Act to:
 - o Extend the time limit on eviction and foreclosure moratorium for homeowners with FHA-insured single-family mortgages;
 - o Provide loan forgiveness for three months for owners of multifamily properties with federally-backed loans;
 - o Allow for the allocated \$4 billion for Homeless Assistance Grants and Emergency Solution Grants to be used for permanent, supportive housing for people experiencing homelessness, and increase the availability and amount of these funds beyond September 2022.

State governments:

- State legislatures should appropriate funds and enact laws to subsidize high-speed, broadband internet for residences and alternative housing, such as homeless shelters or hotels and motels used to provide shelter for those experiencing homelessness.
- State legislatures should appropriate funds and enact laws to provide grants and funds for methods to develop and use technology to monitor ongoing eligibility requirements for public and affordable housing, including rent recalculation for Housing Choice Vouchers.
- State legislatures should appropriate funds and enact laws to provide rental assistance grants to low-income renters and to landlords to reduce evictions and rehabilitate structures with environmental hazards.
- State legislatures should establish or clarify the rule that evictions are limited to where housing owners can demonstrate good cause.
 - o Good cause should be generally limited to a) incidents that threatened the life or well-being of any tenant in the building, or b) a violent crime;
 - o During and for six months after the COVID-19 emergency, good cause should exclude non-payment of rent.

Local governments:

- Courts should interpret emergency orders or declarations regarding evictions broadly, to freeze evictions in all forms and at all stages, including filings and notices.
- Government officials should authorize the use of Homeless Assistance Grant funds received from states via the CARES Act for safe alternative, longer-term housing for people experiencing homelessness that includes supportive services and sanitation measures.
- PHAs should allocate funds to non-profits and mission-driven organizations to provide social services and housing services for low-income renters.
- To prevent public housing tenants from experiencing homelessness, PHAs by rule and/or local governments by ordinance should:
 - o Stop the initiation or completion of evictions for non-violent or emergency reasons until after state or local emergencies are over;
 - o Extend the repayment period to a minimum of six months after the end of the moratorium;
 - o Stop the collection of any late fees during the suggested extended repayment period, even if such fees were charged prior to the beginning of the moratorium;
 - o Eliminate any restrictions on individuals who were evicted from private housing from the Housing Choice Voucher program.
- PHAs should exercise their authority to cease enforcement of any minimum rent during the pandemic and for a period of at least six months after.



About the Author

Courtney Anderson is an Associate Professor of Law at Georgia State University College of Law and her position at Georgia State Law supports the university's Next Generation Initiative, which focuses on interdisciplinary research into how law and policy might impact the social, economic, and environmental determinants of health, particularly among minority and low-income populations. Anderson received an LL.M. with distinction from Georgetown University Law Center in 2012 and graduated from Harvard Law School in 2006.

References

- Benfer, E. (2015). Health Justice: A Framework (and Call to Action) for the Elimination of Health Inequity and Social Injustice. *American University Law Review*, 62(2), 292-293.
- Benfer, E. (2020). Coronavirus Rent Freezes are Ending – and a Wave of Evictions are Sweeping America. Retrieved July 28, 2020, from <https://www.nbcnews.com/think/opinion/coronavirus-rent-freezes-are-ending-wave-evictions-will-sweep-america-ncna1230916>
- Center for Disease Control (2020). COVID-19 in Racial and Ethnic Minority Groups. Retrieved July 28, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html>
- Clifton County (2020). Housing. Retrieved July 28, 2020, from <https://cliftonnj.org/236/Housing>
- Coronavirus Aid, Relief, and Economic Security Act or Pub. L. 116-136, 134 Stat. 281 (2020).
- Couloute, L. (2018). Nowhere to Go: Homelessness Among Formerly Incarcerated People. Retrieved July 28, 2020, from <https://www.prisnpolicy.org/reports/housing.html>
- Eviction Lab (2020). Covid-19 Housing Policy Scorecard. Retrieved July 28, 2020, from <https://evictionlab.org/covid-policy-scorecard/>
- Federal Housing Finance Agency (2020). FHFA Extends Foreclosure and Eviction Moratorium. Retrieved July 28, 2020, from <https://www.fhfa.gov/Media/PublicAffairs/Pages/FHFA-Extends-Foreclosure-and-Eviction-Moratorium-6172020.aspx>
- Garfield, R., Rae, M., Claxton, M., & Orgera, K. (2020). Double Jeopardy: Low Wage Workers at Risk for Health and Financial Implications of COVID-19. Retrieved July 28, 2020, from <https://www.kff.org/coronavirus-covid-19/issue-brief/double-jeopardy-low-wage-workers-at-risk-for-health-and-financial-implications-of-covid-19/>
- Owens-Young, J. (2019). Does Most of Your Paycheck Go to Rent? That May be Hurting Your Health. Retrieved July 28, 2020, from <https://theconversation.com/does-most-of-your-paycheck-go-to-rent-that-may-be-hurting-your-health-113432>
- Poverty USA (2019). Who Lives in Poverty USA. Retrieved July 28, 2020, from <https://www.povertyusa.org/facts>.
- Sisson, P., Andrews, J., & Bazeley, A. (2020). The Affordable Housing Crisis, Explained. Retrieved July 28, 2020, from <https://www.curbed.com/2019/5/15/18617763/affordable-housing-policy-rent-real-estate-apartment>
- Sudeall, L., Pasciuti, D., Ingle, T., & Williams, K. (2020). Courts in Crisis Exploring the Impact of COVID-19 on Eviction Court in Georgia. Retrieved July 28, 2020, from <https://law.gsu.edu/document/courts-in-crisis-exploring-the-impact-of-covid-19-on-eviction-court-in-georgia/?wpdmdl=199029>
- United States Department of Housing and Urban Development (2020). COVID-19 FAQs for Public Housing Agencies
- Urban Institute (2020). The Renters and Rental Market Crisis Working Group. Retrieved July 28, 2020, from <https://www.urban.org/renters-and-rental-market-crisis-working-group>
- Washoe County (2020). COVID-19 Washoe Response to Homeless Services. Retrieved July 28, 2020 from <https://covid19washoe.com/covid-19-washoe-response-to-homeless-services/>

Protecting Workers that Provide Essential Services

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SUMMARY. States and localities, which retain the right to protect the health and safety of their citizens, have designated more than 55 million Americans as “essential workers” during the COVID-19 pandemic. Most essential workers are employed in health care (30%) and in food and agricultural (21%) (McNicholas & Poydock, 2020). A majority (76%) of all essential health care workers are women, while half of all essential food and agricultural workers are racial and ethnic minorities. Consequently, many women and racial and ethnic minorities are unable to shelter at home or socially distance themselves because they are deemed “essential workers” (Yearby & Mohapatra, 2020). Even though these workers are deemed “essential workers,” they have not been provided with the employment and safety protections (e.g., paid sick leave, health insurance, and workers’ compensation) that are essential to keeping them and their families healthy and safe. To address the lack of economic protections, which is discussed in more detail in Chapter 28, essential workers should be provided with a guaranteed basic income, paid sick leave, health insurance coverage, and survivorship benefits regardless of their worker and/or immigration status (Yearby & Mohapatra, 2020). To keep workers from being killed or otherwise harmed at work, the government (federal and state) must issue mandatory health and safety laws and regulations that are aggressively enforced to prevent workplace COVID-19 infections and deaths. Finally, to ensure that essential workers and their families do not suffer financially if they contract COVID-19, the government (federal and state) and businesses should be financially responsible for the harm caused as a result of a worker’s COVID-19 infection or death.

Introduction

Most essential workers (51%) are employed in hospitals, long-term care facilities, meat and poultry processing facilities, and farms, which have been hotspots for COVID-19 infections. Yet, these workplaces were not safe even prior to COVID-19. For example, “in 2017 meatpacking workers were nearly twice as likely to suffer an injury and more than 15-times as likely to suffer an occupational illness than the average private sector worker – the second-highest rate of occupational illness among all US industries” (Human Rights Watch, 2019). Agriculture workers also suffer exposure to mold and numerous work-related injuries, including musculoskeletal disorders, eye damage, respiratory conditions, heat stress, and acute and chronic poisoning from pesticides (Schoch-Spana et al., 2010). The additional threat of contracting COVID-19 in the workplace has exacerbated these disparities in workplace injuries.

As of July 27, 2020, more than 113,731 health care personnel have tested positive for COVID-19 and 576 have died (CDC, 2020), while over 31,000 food and agricultural workers have tested positive for COVID-19 and 101 have died (Held, 2020). A majority of the workers in hospitals, long-term care facilities, meat and poultry processing facilities, and farms are women and racial and ethnic minorities who live in poverty and do not have paid sick time. For example,

agricultural workers live below the poverty level, do not have paid sick leave, and tend to be immigrants from countries such as Mexico, Central America, and the Caribbean who work in 42 of the 50 states, including California, Illinois, Texas, and Washington (Schoch-Spana et al., 2010).

Direct care workers are primarily women of color (59%), live in poverty (18%), rely on some form of public assistance including food stamps and Medicaid (53%), and do not have paid sick leave (The Commonwealth Fund, 2020). Moreover, 51.5% of those who are considered frontline meatpacking workers are immigrants, compared with 17% of all workers in the United States. Since women and racial and ethnic minorities make up the majority of these workers, they have been disproportionately harmed by COVID-19 (Yearby & Mohapatra, 2020). This is in part a result of agency understaffing.

Under the Trump administration, the number of Occupational Safety and Health Administration (OSHA) inspectors charged with protecting the health and safety of a majority of workers has been at the lowest recorded level since 1975, and 42% of OSHA’s top leadership positions remain unfilled (Held, 2020). Due to this understaffing, OSHA has conducted 5,000 fewer inspections per year than during the Obama and Bush administrations.

Furthermore, although most workers’ compensation laws do not cover infectious disease, many states have enacted business liability shield laws that limit workers’ ability to sue their employers for workplace harms related to the COVID-19 pandemic. Consequently, many essential workers are not receiving the protections they need to stay safe and healthy during the COVID-19 pandemic. This report identifies and examines the major problems with the government’s response to protecting the health and safety of essential workers during the COVID-19 pandemic and provides recommendations to address these problems.

Worker Safety During COVID-19

The purpose of worker health and safety laws is to protect workers from being killed and otherwise harmed at work. Federal and state occupational safety and health agencies normally enforce worker health and safety laws. However, during the COVID-19 pandemic, the Centers for Disease Control and Prevention (CDC) and state legislators and governors have also been involved. The gaps in each response and its impact on workers’ health and safety are discussed below.

OSHA and States

The Occupational Safety and Health Act of 1970, 29 U.S.C. § 651 et seq., (OSH Act) created OSHA and provided the agency with the authority to regulate the health and safety of all workers, except independent contractors and state and local government employees. The 21 states listed in Table 26.1 have OSHA-approved plans governing private and government workers and thus retain sole authority to address OSHA matters. OSHA retains authority to enforce federal occupational and health laws and regulations to protect private workers in the remaining 28 states and the District of Columbia.

Under the OSH Act, OSHA and the 21 states with OSHA-approved plans have the power to require employers to provide employees with personal protective equipment and develop a respiratory protection standard to prevent occupational disease (29 C.F.R. § 1910.134). Moreover, employers have a “general duty” to provide employees with a place of employment free from recognized hazards that are causing or likely to cause death or serious harm (OSH Act, 1970).

However, the OSH Act does not cover many direct care workers and some agricultural workers because they are classified as independent contractors. Even if the OSH Act does apply, it is insufficient to address COVID-19 because neither the respiratory standard nor the general duty clause requires employers to conduct

a worksite hazard assessment to determine how an airborne infectious disease can spread within the worksite or adopt specific measures to limit the spread of the airborne infectious disease in the worksite. OSHA noted the inadequacies of these laws to address airborne infectious diseases, like COVID-19, in its 2010 Infectious Diseases SER Background Document discussing a proposed airborne infectious disease rule.

In fact, OSHA has been developing an airborne infectious disease rule since 2005 that would fill these gaps and have a “direct benefit on reducing occupational illness rates for covered workers, but also have the ancillary benefit of reducing illness rates for patients and other individuals, such as family members, who come into contact with covered workers.” Although the rule was shelved in 2017, OSHA still has the power to issue an emergency temporary standard (ETS) to take immediate effect if it determines either that employees are exposed to grave danger from new hazards or that such emergency standard is necessary to protect employees from danger (OSH Act, 1970).

In March, members of Congress and numerous unions representing essential workers employed in the health care, food, and agricultural industries petitioned OSHA to issue an ETS, yet OSHA declined. The unions even filed a lawsuit to force OSHA to issue an ETS. Yet, the United States Court of Appeals for the D.C. Circuit ruled against the unions, stating that OSHA reasonably determined that an ETS was not necessary because of the regulatory tools that OSHA has to ensure that employers were maintaining hazard-free work environments (“American Federation of Labor and Congress of Industrial Organizations v. OSHA,” 2020).

However, contrary to the court’s ruling, OSHA’s current regulatory tools do not ensure that employers are maintaining hazard-free work environments as discussed above. None of the current laws and regulations gives OSHA the authority to mandate testing of workers even after it has been shown that a worker is infected with COVID-19 or to slow down work speeds in meat and poultry processing facilities to support social distancing. Moreover, although workers have filed over 5,000 complaints regarding workplace hazards that increase the risk of COVID-19 infection, OSHA has only issued one citation related to the pandemic and closed many of these complaints without in-person inspections (Held, 2020). Instead OSHA has relied on employers to make a “good faith” effort to comply with its advisory worker health and safety guidance rather than issue mandatory requirements or conduct in-person inspections (O’Scannlain, 2020).

Table 26.1: States with OSHA-approved plans for private and government workers

Alaska	Arizona	California	Hawaii	Indiana
Iowa	Kentucky	Maryland	Michigan	Minnesota
Nevada	New Mexico	North Carolina	Oregon	South Carolina
Tennessee	Utah	Vermont	Virginia	Washington
Wyoming				

Some states, like Illinois, have been conducting on-site health and safety inspections at hospitals. In addition, the Michigan governor enacted an executive order to provide health and safety protections for agriculture workers. Yet, there are still gaps in OSHA and state’s worker health and safety protection measures.

Worker Health and Safety Guidance: OSHA and CDC

OSHA, in partnership with the CDC, has issued numerous advisory worker health and safety guidance for workers and employers as a means to protect to worker health and safety. All of the guidance discuss very similar issues, such as the potential for workplace exposure and the need to create a COVID-19 assessment and control plan. Nevertheless, the guidance are not comprehensive and fail to recommend testing of all workers once a worker tests positive for COVID-19. Mandating testing of all workers after identification of an infected worker is necessary to track all worker infections as well as prevent the spread of COVID-19.

For example, after nearly two-dozen workers were hospitalized, Tyson Foods closed its Waterloo, IA pork processing plant in late April and tested all the workers. The testing showed that 1,000 workers were positive for COVID-19, including many who did not show any symptoms. Hence, without testing, the number of workers infected would not have been known and asymptomatic workers would have continued to spread the disease. Since then, Tyson has tested almost every worker at its 20 facilities. However, this is just one business that chose to conduct testing. Without mandates or even suggestions for testing in the OSHA/CDC guidance, there is no way to know the occupations most impacted

by COVID-19 or guarantee that other businesses will test essential workers and disclose the results. In fact, agricultural workers at a pistachio farm in California didn’t know coworkers had tested positive for COVID-19 until they learned it from the media.

Worker health and safety is further compromised by the delay in issuing guidance. In mid-April, there were already signs of outbreaks tied to agriculture businesses as evidenced by the 100 COVID-19 cases linked to a produce-processing plant in Rhode Island. However, the guidance for agricultural workers was not issued until June 2, 2020. By that time over 2,076 agricultural workers in New York, 1,948 in California, and over 1,000 in Illinois, Texas, Iowa, Washington, and Minnesota were infected with COVID-19 (Sowder, 2020). Hence, for some essential workers, the guidance have been woefully late.

Furthermore, none of the recommendations are mandatory. In fact, all of them state that the “guidance is not a standard or regulation, and it creates no new legal obligations. ... The recommendations are advisory in nature, informational in content, and are intended to assist employers in providing a safe and healthful workplace” (CDC & OSHA, 2020). Even though all the guidance also say that employers are required to comply with the OSH Act’s general duty clause, it is unclear what recommendations are mandatory because none of the recommendations are linked to the general duty clause.

Thus, employers are free to ignore the guidance, which has left many workers, especially essential workers, susceptible to COVID-19 infection at their workplace. State laws have also left essential workers unprotected.

Table 26.2: States with Business Liability Laws

STATES	BUSINESS SHIELD LAWS
Alabama	Proclamation by governor; Workers must show clear and convincing evidence that COVID-19 exposure was caused by the businesses’ wanton, reckless, willful, or intentional misconduct and damages for serious harm are limited to actual economic compensatory damages.
Iowa	Act; Limits recovery for workplace COVID-19 exposure to acts that were intended to cause harm or constitute actual malice, but provides a safe harbor if the business complied with either a federal or state statute, regulation, order, or public health guidance related to COVID-19.
North Carolina	Act; Limits recovery for COVID-19 exposure to acts that consisted of gross negligence, reckless misconduct, or intentional infliction of harm, but allows for claims under workers’ compensation.
Oklahoma	Act; Limits recovery for COVID-19 exposure if the business was in compliance with federal or state regulations, a presidential or gubernatorial executive order, or guidance.
Utah	Act; Limits recovery for COVID-19 exposure to acts that consisted of willful misconduct, reckless infliction of harm, or intentional infliction of harm, but allows for claims under workers’ compensation.
Wyoming	Act; COVID-19 infection of workers is presumed to happen at work so employees are eligible for workers’ compensation; limits business liability for those who in good faith followed instructions of a state, city, town, or county health officer.


State Laws

Many states have begun to issue laws and policies to provide businesses with liability shields from worker COVID-19 lawsuits, which are summarized in Table 26.2.

The laws in North Carolina, Utah, and Wyoming specifically note that the liability shield does not impact workers’ compensation. Although workers’ compensation laws are different in each state, most states provide workers injured on the job with wage replacement benefits, medical treatment coverage, vocational rehabilitation, and a settlement if the injury leaves the worker permanently disabled. California, Michigan, and Kentucky passed laws making it easier for all employees to prove workplace COVID-19 exposure so they can receive workers’ compensation.

In other states it is unclear whether state worker’s compensation laws

provide coverage for workplace infectious disease outbreaks. Many states exclude the “ordinary disease of life,” such as a cold or the flu, yet the COVID-19 pandemic seemingly goes beyond the “ordinary disease of life” (National Council on Compensation Insurance, 2020). Virginia’s law specifically notes that an infectious or contagious disease is covered under worker’s compensation, yet many states have not provided such clarification (VA Code Ann §65.2-401, 1997). Furthermore, although many states have expanded workers’ compensation, like in Missouri and Washington, to cover COVID-19 infection, some of these laws are limited to first responders or health care personnel (NCCI, 2020).

Without clarification of the workers’ compensation laws and coverage for all essential workers, liability shields will leave many essential workers without compensation to cover missed wages and to pay for health insurance if they contract COVID-19 in the workplace. To fill the gap, states should make it easier for all essential workers to obtain worker’s compensation for workplace COVID-19 exposure. Alternatively, the federal government could enact the Pandemic Risk Insurance Act, creating a national COVID-19 workers compensation system (NCCI, 2020). 

Recommendations for Action

Federal government:

President and Congress should

- Enact a national paid sick leave law, not limited by worker status or employer size, with retaliation protection.
- In all laws and regulations enacted to shield businesses from liability, include worker economic and safety protections including, but not limited to hazard pay, death benefits, workers' compensation for COVID-19 infections, mandatory infectious disease protections, and significant increased funding and authority for enforcement of worker health and safety laws.
- Enact law giving OSHA authority to address food production speeds to enable social distancing.
- Enact the Pandemic Risk Insurance Act, creating a national COVID-19 workers compensation system.

OSHA and States with OSHA Approved Plans should

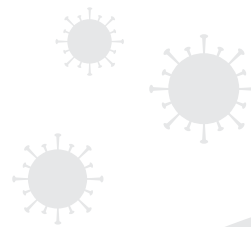
- Adopt an emergency temporary standard based on the proposed airborne infectious disease rule.
- Publish a final rule based on the proposed airborne infectious disease rule that includes the authority to regulate food production speeds.
- Make complaint data publicly available and disaggregate by industry to determine businesses that are hotspots for COVID-19.
- Conduct in-person inspections of business that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities.
- Mandate testing of workers employed at businesses that are hotspots for COVID-19, including, but not limited to hospitals, long-term care facilities, meat and poultry processing facilities, farms, and food processing facilities.

OSHA and CDC should

- Track COVID-19 infections and deaths by occupation to determine what workers are most impacted by COVID-19.
- Mandate testing of all workers after identification of an infected worker to prevent the spread of COVID-19 at workplaces.

State governments:

- Should enact statewide paid sick leave requirement, not limited by worker status or employer size, with retaliation protection for those not covered by a national law.
- In all laws and regulations enacted to shield businesses from liability, states should include worker economic and safety protections including, but not limited to hazard pay, death benefits, workers' compensation for COVID-19 infections, mandatory infectious disease protections, and significant increased funding and authority for enforcement of worker health and safety laws.



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References

- American Federation of Labor and Congress of Industrial Organizations v. Occupational Safety and Health Administration, 2020 WL 3125324 (US Ct. of Appeals, DC Circuit 2020).
- Centers for Disease Control and Prevention (CDC)(2020). Cases in the U.S. Retrieved July 27, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html>
- Centers for Disease Control and Prevention and the Occupational Safety and Health Administration (CDC & OSHA)(2020). Agriculture Workers and Employers Interim Guidance. Retrieved July 27, 2020, from <https://www.cdc.gov/coronavirus/2019-ncov/community/guidance-agricultural-workers.html>
- Held, L. (2020). OSHA Faulted for Not Doing More to Protect Workers from COVID-19. Retrieved July 15, 2020, from <https://civileats.com/2020/06/16/osha-faulted-for-not-doing-more-to-protect-workers-from-covid-19/>
- Human Rights Watch (2019). When We're Dead and Buried, Our Bones Will Keep Hurting: Worker Rights Under Threat in US Meat and Poultry Plants. Retrieved July 15, 2020, from <https://www.hrw.org/report/2019/09/04/when-were-dead-and-buried-our-bones-will-keep-hurting/workers-rights-under-threat#>
- McNicholas, C., & Poydock, M. (2020). Who are Essential Workers? A Comprehensive Look at Their Wages, Demographics, and Unionization Rates. Retrieved July 15, 2020, from <https://www.epi.org/blog/who-are-essential-workers-a-comprehensive-look-at-their-wages-demographics-and-unionization-rates/>
- National Council on Compensation Insurance (NCCI)(2020). NCCI's Compensability – Statutory Survey. Retrieved July 27, 2020, from <https://www.ncci.com/Articles/Pages/Insights-Coronavirus-FAQs.aspx#>
- O'Scannlain, K. (2020). U.S. Department of Labor News Release, Statement of Enforcement Policy by Solicitor of Labor Kate O'Scannlain and Principal Deputy Assistant Secretary for OSHA Loren Sweatt regarding Meat and Poultry Processing Facilities. Retrieved July 15, 2020, from <https://www.dol.gov/newsroom/releases/osha/osha20200428-1>
- Schoch-Spana, M., Bouri, N., Rambhbia, K., & Norwood, A. (2010). Stigma, Health Disparities, and the 2009 H1N1 Influenza Pandemic: How to Protect Latino Farmworkers in Future Health Emergencies. *Biosecurity and Bioterrorism: Biodefense Strategy, Practices, and Science*, 8(3), 243-254.
- Sowder, A. (2020). COVID-19 Cases Mount as Summer Harvesting Heats Up. Retrieved July 15, 2020, from <https://www.thepacker.com/article/covid-19-cases-mount-summer-harvesting-heats>
- The Commonwealth Fund (2020). The Invisible COVID Workforce: Direct Care Workers for Those with Disabilities. Retrieved July 27, 2020, from <https://www.commonwealthfund.org/blog/2020/invisible-covid-workforce-direct-care-workers-those-disabilities>
- Yearby, R., & Mohapatra, S. (2020). Law, Structural Racism, and the COVID-19 Pandemic. *Journal of Law and the Biosciences* (forthcoming).

Liability and Liability Shields

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SUMMARY. This Chapter first examines the liability of businesses and medical professionals for acts and omissions involving COVID-19 mitigation, treatment, and reopening. Second, it provides an analysis of the federal and state liability shields, those that were in existence before COVID-19, those introduced more recently, and calls for more and broader shields. Claims will be brought by consumers (predominantly nursing home residents) alleging that businesses failed to protect them, patients treated at the height of the pandemic when emergency departments were overrun, and consumers who contract the virus during reopening. There are few federal liability shields applying to private actors, the most important being the PREP Act of 2005. A substantial number of states have adopted some type of liability waiver specifically related to the COVID-19 pandemic, initially providing immunity protections for health care providers and more recently protecting businesses as they reopen. Many of the health care providers shields present difficult questions of interpretation, particularly with regard to whether they are limited to emergency triage decisions, mitigation, or treatment efforts in contrast to broader acts or omissions that may have contributed to the infection outbreak, such as poor hygiene control. There is no evidence that a broad federal shield is necessary. State policymakers also should resist calls for broader shields and should provide transparent, data-driven guidance on reopening which can inform the existing and appropriate reasonable care standard. Court should carefully scrutinize the constitutionality of shields and not show the same deference as given to prior tort reform legislation.

Introduction

This Chapter examines the potential liability of businesses and medical professionals for acts and omissions involving COVID-19, and provides an analysis of long-established, new and contemplated federal and state liability shields. This Chapter does not cover lawsuits against essential businesses that stayed open during the first peak of the pandemic emergency orders. Large numbers of claims are likely to be pursued by employees in high-risk industries (for example, meatpacking or warehouse fulfillment).

Potential Targets of COVID-19 Lawsuits

Typical COVID-19 lawsuits against businesses or their employees will allege either that the defendant's act or omission caused the plaintiff to contract the virus or that the defendant's act or omission in mitigating or treating the virus caused injury or death. Most lawsuits claim that the defendant's failure to act with reasonable care caused the plaintiff's injuries (negligence). The standard of care in most cases will be ordinary negligence, posing the jury question whether the defendant acted as a reasonable person in all the circumstances. Cases brought against health care providers may be categorized as medical malpractice and turn on expert testimony as to the professional standard of care. A few cases will be brought alleging intentional or willful actions, possibly in an attempt to trigger exceptions in liability shields.

There may even be idiosyncratic intentional tort actions brought by persons against those they believe transmitted the virus to them intentionally or recklessly; these will resemble some of the cases brought against people living with HIV.

Businesses may be sued by customers alleging failure to protect them from COVID-19. The only substantial number of claims in this cohort likely will come from nursing home residents or their families. In most cases these will be ordinary negligence claims based on, for example, substandard infection control, failure to isolate residents with symptoms, and sub-optimal staffing. In many cases these negligence claims will be fortified by alleged breaches of state or federal regulatory standards applicable to long-term care facilities. Press reports have suggested that several nursing homes failed to report COVID-19 cases or refused to update families about residents' conditions; in such cases allegations of reckless or negligent infliction of emotional distress may have traction. Finally, nursing homes, as recipients of Medicaid funds, also are likely to face False Claims Act claims alleging inadequate care or some form of regulatory non-compliance. Such actions are often initiated by whistleblowers, are notoriously difficult to defend, and usually result in very large settlements.

Health care providers are another likely target. During pandemic peaks, emergency departments have been overrun and patient care threatened by shortages of staff, personal protective

equipment (PPE), beds, intensive care unit (ICU) beds, and ventilators. As providers, many of whom were practicing outside of their usual specialties, used improvised equipment and even prescribed untested drugs, it is highly likely that avoidable adverse events occurred. No doubt, some of those adverse events involved rationing of care.

Finally, medium to high-risk businesses reopening after the lifting of government restrictions clearly face legal jeopardy if their customers contract COVID-19. The most obvious examples are restaurants, gyms, personal care services, schools, and colleges. Similar questions apply to businesses that kept open only their essential services open while closing others. For example, as hospitals reopen for routine care or elective surgeries, patients face the risk of COVID-19 as a hospital-acquired infection.

Liability Shields

The devastation caused by COVID-19, unknowns that remain regarding its transmission and pathology, and disagreements about reopening all create uncertainty. It is perhaps understandable that those facing potential lawsuits will seek immunity. Less admirable are opportunistic stakeholders with imperfect safety records seeking broad immunity for acts or omissions that caused harm. Orthogonal to shields granted by federal or state governments are those that potential defendants (particularly those in the process of reopening) are attempting to impose on their customers. Such exculpatory clauses or waivers releasing defendants from liability for injury or damages resulting from negligence are sometimes referred to as express assumption of the risk. Many states allow these waivers to operate as an affirmative defense in situations where the activity is discretionary and recreational (such as skydiving) as opposed to necessary (such as health care). There are reports of theme parks and political rallies posting notices that entrants assume COVID-19 risks, and of gyms and salons incorporating them into their contracts. This is an emerging area that may require further treatment as reopening continues.

Federal Shields. Liability shields for private actors under federal law are limited. The Public Readiness and Emergency Preparedness (PREP) Act of 2005 applies to “covered countermeasures,” principally drugs, devices, and vaccines used to fight a national emergency that cause death or serious physical injury, and shields manufacturers and others in the supply chain. In addition to immunity, PREP includes the Countermeasures Injury Compensation Program (CICP) that provides benefits to individuals who sustain a serious physical injury or die. In March 2020 the PREP Act was amended by the Families First Coronavirus Response Act to include “personal respiratory protective devices.”

The Volunteer Protection Act (VPA) of 1997 immunizes volunteers who work for non-profits or government entities. An emergency declaration is not required. The CARES Act of 2020 introduced a broader immunity for volunteering health care professionals without limitation as to workplace. This also has misconduct exceptions. Unlike the VPA, the CARES immunity only applies during the COVID-19 state of emergency.

This Chapter concentrates on shields providing immunity from negligence claims. In the longer term and perhaps of greater importance will be legal issues arising around a COVID-19 vaccine. Vaccines, like drug treatments for COVID-19, raise products liability issues (that is, liability for causing harm without proof of negligence). In the case of vaccines, the National Childhood Vaccine Injury Act already shields manufacturers and provides a no-fault compensation scheme for those who suffer vaccine-related injuries. That legislation could provide a useful model for expanded coverage to incentivize maximum participation in vaccination.

State Shields. In addition to the limited federal liability shields, most states provide some type of immunities that apply during declared emergencies and that were enacted prior to COVID-19. Almost all states have adopted some variant of the Model State Emergency Powers Act. Its immunity protects private actors who render “assistance or advice at the request of the State.” These existing emergency immunity laws typically were triggered by the state COVID-19 emergency declaration.

A substantial number of states have adopted liability waivers related to the pandemic. The first group of waivers (“health care shields”), adopted as the threat of the pandemic became clearer, provide immunity protections for health care providers. As of early June 2020, 21 states had COVID-19-specific health care shields, some introduced by legislation, most by temporary executive or emergency orders. A second group (“reopening shields”), so far adopted by few states, leans towards more comprehensive immunity for particular industries, such as long-term care and colleges. For example, Utah’s statute shields the owners and operators of premises, broadly defined, while Louisiana’s first reopening shield applied only to restaurants. Beyond state shields there have been calls for a broad federal shield. Such legislation is unprecedented, would face major obstacles in Congress, and is likely unconstitutional.

Assessment Liability

The three types of actions we can most safely predict are those alleging negligence against nursing homes and other care facilities, avoidable adverse events that occurred during the height of the pandemic, and disease transmission to consumers of reopening businesses.

Liability shields aside, these are not going to be easy cases to win. Plaintiffs will face difficulty in establishing causation. Given the nature of COVID-19, viral transmission remains possible even where reasonable care is taken; proving that a lack of care caused transmission is therefore problematic. Further, while a concurrent cause, such as a pre-existing lung disease, would not rule out liability, the unique and unknown features of the virus combined with multiple co-morbidities will create problems of proof for many plaintiffs.

Nursing homes admissions contracts frequently include binding arbitration clauses that bar lawsuits. Health care providers also

benefit from decades of state legislative action making them more difficult to sue or reducing damages. Cases that involve care or treatment will often require plaintiffs to introduce expert testimony from other health care providers as to the standard of care. In contrast, cases involving the maintenance of premises, including infection control, are less likely to be classified as professional negligence, leaving the question of “reasonable care” to the jury. The standard of ordinary or professional care also is qualified by the phrase “in all the circumstances.” Evidence of extenuating circumstances at the height of the pandemic such as emergency rooms operating well above capacity and shortages of ICU beds and ventilators likely would be admissible to prove the defendant’s behavior was reasonable.

Reopening businesses are likely at greater legal risk. Those that cannot comply with reopening protocols because their size or architecture makes social distancing or other established reopening norms impossible face difficult choices. The reasonable care standard, based on balancing risks and benefits, suggests it would be negligent for them to reopen: financial suffering, while real, does not feature in negligence law’s analysis. In contrast, those who reopen in conformity with state-level guidelines should be able to point to their compliance as evidence of non-negligence. More difficult questions will arise where plaintiffs argue that local or state guidelines are themselves deficient (or mutually inconsistent) and that they do not reflect reasonable care.

Shields

The effectiveness and appropriateness of the shields turns on their scope. Written as they were during a rapidly emerging pandemic, they are not always clear as to their (usually limited) intent nor do they use common phraseology. Those written during reopening are broader in scope. The scope questions most likely to arise for judicial determination are which cohorts are protected and the extent to which the defendant’s conduct must arise from COVID-19 emergency treatment or state ordered mitigation.

Overall, the intent of most of the early provisions is reasonably clear; they are designed to protect front-line health care workers and health care facilities from negligence liability. Almost without exception the shields negate the immunity in cases of willful, criminal, or reckless conduct.

The broadest health care liability shield, and one that that health care provider and nursing home lobbyists reportedly helped draft, is New York’s Emergency or Disaster Treatment Protection Act of 2020. It explicitly immunizes health care professionals and facilities, including nursing homes, home care services, and even health care facility administrators and executives. However, most health care shields have narrower lists of protected persons. While generally more restrictive, most shields apply to health care workers and facilities, but few expressly include nursing homes or EMTs.

Perhaps the most difficult interpretative issue and one certain to be litigated, is the extent to which the immunity is tied to or arises from pandemic-related services. For example, most tie the immunity to “providing medical services in support of the state’s

public health emergency for COVID-19,” although few go further, applying to the treatment of “a patient for the illness or condition that resulted in the declared major public health emergency.” This “arising from” type of question will lead plaintiffs to argue shields only protect from lawsuits involving emergency triage decisions, mitigation, or treatment efforts. In contrast, defendants such as nursing homes will argue the immunity also applies to liability for acts or omissions that contributed to an outbreak, such as poor hygiene control.

Reopening shields are less likely to pose such interpretative questions. These broad modifications to premises liability will employ language similar to that used in the Utah statute: “a person is immune from civil liability for damages or an injury resulting from exposure of an individual to COVID-19 on the premises owned or operated by the person.” However, reopening shields may face constitutional challenges. State tort reforms, particularly medical malpractice reforms, generally have survived due process and equal protection scrutiny. However, those reforms stopped at adding procedural barriers or capping pain and suffering damages. Banning all lawsuits against a large number of businesses is a far more radical step and lacks a strong rationale. It is difficult to see the public interest in immunity when reopening using reasonable care as laid out in public health protocols will better serve the public.

The public interest question goes to the heart of the normative questions raised by liability shields. Liability models (whether framed in strict liability, ordinary negligence, or professional negligence) reflect how we wish to distribute risks between cohorts (e.g., nursing homes and residents). Negligence liability (particularly professional liability) favors defendants over plaintiffs. Defendants such as health care providers and retail businesses can externalize some risks through the purchase of liability insurance, while injured patients and consumers have no equivalent mechanisms beyond the uncertainties surrounding their own health insurance. Does a pandemic require recalibration of those models to further favor defendants?

The easiest question to answer is the call for immunity from the nursing home industry. Nursing homes did not cause the pandemic, but poor infection control, inadequate staffing and sluggish mitigation allowed the virus to spread. And skilled nursing homes have received a \$4.9 billion distribution from the CARES provider fund. There is no evidence that the lawsuits filed are “frivolous,” the reasonable care standard is overly burdensome, or that damage awards are out of control. This is simply an opportunistic move by an industry with a terrible safety record (Sklar and Terry, 2020).

The question of freeing health care providers from liability while working in emergency rooms and the like is more finely balanced. On one side, there is some evidence that too many facilities were unprepared for any serious emergency. Also, the “in all the circumstances” portion of the reasonable care standard should keep the number of lawsuits in check without any special immunity. Further, there is already abundant evidence that COVID-19 has disproportionately impacted already vulnerable populations and persons of color; should the legal system pile on by immunizing some actors?

On the other hand, the way clinicians were pressed into service in northeastern states suggests that it is appropriate to cut off liability predicated on technical issues such as a lack of licensure in that state or exceeding the scope of practice. Recalibration is particularly meritorious in cases of volunteers drafted in from other states who may not have liability coverage in the state they end up working. It may also be appropriate to reduce the malpractice anxiety for providers facing novel and extreme conditions, like reusing PPE, or having to prioritize one patient's survival over another's, that neither training nor customary standards address.

Finally, there are some arguments in favor of reopening shields. To a large extent calls for shields are born of uncertainty about what precautions will protect from liability. Some, but by no means the majority of states are performing data-driven reopening with calibrated safeguards. To what extent do liability rules synchronize with those policies? Are the risks liability rules impose on businesses inconsistent with reopening, thus justifying a shield? Will immunities for businesses encourage customers or drive them further away?

The answer, of course, depends on the shield. Blanket immunities protect irresponsible businesses at the expense not only of their consumers but also their responsible competitors. Equally, equity considerations suggest that, if any businesses should be shielded, they should not be large, well-resourced corporations but small locally-owned ones owned by those in the community. While the sensible conclusion must be that the reasonable care standard is appropriate even (and maybe even particularly) in a pandemic, non-blanket reopening immunities may have a role to play. Legislation that premises immunity on compliance with generally accepted reopening standards, such as those from the CDC are more appropriate. However, to keep the playing field level, the burden of showing compliance with external, objective standards should remain with the business seeking to rely on them. 🌞

Recommendations for Action

Federal government:

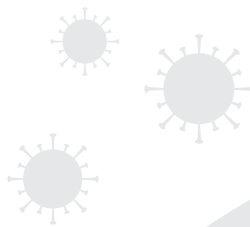
- There is no evidence that a broad federal shield is necessary. Demands for such not only are unwarranted but also typify unconscionable, opportunistic behavior by industries with poor safety records.
- A broad federal shield is unprecedented, would face major obstacles in Congress, and is likely unconstitutional.
- Any limited immunity granted at the federal level (for example, to protect vaccine manufacturers and prescribers) should be carefully calibrated and include a federal compensation scheme.

State governments:

- Calls for broader immunity shields should be resisted, particularly where the conduct for which the shield is sought was not in mitigation of the pandemic but actually increased the transmission.
- State policymakers would better serve businesses and other stakeholders not by providing immunity from unreasonable care but by reducing uncertainty with transparent, data-driven guidance on reopening and allowing that to inform the existing and appropriate reasonable care standard.

Courts:

- Should interpret emergency COVID-19 shields narrowly to avoid creating unjustifiably broad immunities, recognize they were designed to protect front-line workers during a limited period of unprecedented demand, stress, and shortness of supplies.
- Should carefully scrutinize the constitutionality of shields and not show the same deference to legislative action given to malpractice reform.
- Courts should void the exculpatory clauses being inserted into theme park and other contracts. First, they should be denied applicability unless they explicitly exclude liability for failing to take reasonable care. Second, where they impact services of general public interest (such as political rallies) or necessity they fall outside the narrow category of recreational activities and should be voided.



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References

- Coronavirus Aid, Relief, and Economic Security Act (CARES) Act of 2020, H.R. 748, 116th Cong. (2019-2020), Sec. 3215.
- Model State Emergency Health Powers Act (MSEHPA) of 2001. Retrieved July 3, 2020, from <http://www.publichealthlaw.net/MSEHPA/MSEHPA.pdf>
- National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to 300aa-34 (1986).
- New York Emergency or Disaster Treatment Protection Act, NY Public Health Law §3080 et seq. (2020).
- Public Readiness and Emergency Preparedness (PREP) Act of 2005, 42 U.S.C. 247d-6d (2005).
- Sklar, T., & Terry, N.P. (2020). States are Making it Harder to Sue Nursing Homes Over COVID-19: Why Immunity From Lawsuits is a Problem. , The Conversation. Retrieved July 3, 2020, from <https://theconversation.com/states-are-making-it-harder-to-sue-nursing-homes-over-covid-19-why-immunity-from-lawsuits-is-a-problem-139820>
- Utah S.B. 3007, enacting Utah Code Ann. §78B-4-517.
- Volunteer Protection Act (VPA) of 1997, 42 U.S.C. §14503 (1997).

Protecting Workers' Jobs and Income During COVID-19

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SUMMARY. The COVID-19 pandemic has exposed and exacerbated the harmful impacts of disparities in access to workplace supports like paid leave and unemployment benefits, and has led to worsening economic conditions for people already living on the margins. Workers in the United States have long experienced a crisis around care – too often having to risk their jobs and income when they or their loved ones become ill. The United States is one of the only countries in the world without universal, guaranteed, job-protected paid leave. A complex patchwork of laws allows some workers to take time off work to care for themselves and their families, but low-wage workers are often excluded from coverage or otherwise face barriers to accessing these protections. The unemployment insurance system provides temporary, partial wage replacement to those who lose their jobs through no fault of their own. But some workers, including undocumented immigrants, are excluded, and cumbersome rules and administrative obstacles prevent many others from accessing benefits. In March 2020, Congress enacted temporary emergency paid sick and family leave for the first time, as well as expanded unemployment benefits, but both programs have serious gaps that disproportionately impact women, people of color, low-income workers, and immigrants. This Chapter examines the income and job protection policy responses to COVID-19 and recommends additional solutions that center the needs of low-wage workers and families, and prioritize racial and gender equity and access for immigrants.

Introduction

Income and Job-Protection Policies Before the Pandemic

Until the pandemic, the United States stood out as one of the only countries in the world without any guaranteed right to paid sick days (WPAC, 2020) or paid parental leave (Livingston & Thomas, 2019).

Since 1993 the Family and Medical Leave Act (FMLA) has provided 12 weeks of unpaid, job-protected leave, with continued health insurance, to address a worker's own or a family member's serious health condition or to bond with a new child. FMLA was amended in 2008 to also cover military caregiving leave. But at least 40% of workers do not qualify for FMLA given the law's strict requirements (50+ employees within 75 miles, one year of service, and 1,250 hours worked in the prior year). Low-wage workers are disproportionately excluded. Even among those who qualify, most cannot afford to take unpaid leave. Sixty-one percent of Black adults, 67% of American Indian and Alaska Native adults, and 71% of Latinx adults are either ineligible for or cannot afford to take unpaid FMLA leave, compared to 59% of white adults (Joshi et al., 2020). Moreover, FMLA is narrow, allowing leave only to address serious illnesses or new child bonding and covering only parents, spouses, and minor children. The law does not contemplate care needs because of school closures, or bereavement leave.

The Americans with Disabilities Act (ADA) requires employers with at least 15 employees to provide reasonable accommodations, which can include unpaid leaves of absence, to a worker with a disability, unless it would pose an undue hardship. However, employers are not required to continue health insurance under the ADA.

Some states have their own job protection and disability accommodation laws. Eight states and the District of Columbia have enacted paid family and medical leave laws, and 13 states have enacted paid sick days laws, with many localities providing more sick days than offered under state law. Some employers voluntarily provide paid leave. But millions of workers are either not covered by or face barriers accessing these benefits, and those earning low wages often have the least access. Among civilian employees in 2019, only 31% of the lowest wage workers had access to paid sick days, compared to over 90% of the highest earners (DeSilver, 2020). As of 2019, only 5% of the lowest wage workers had access to any paid family leave through their employers, compared to 30% of the highest earners (BLS, 2020). Forty-eight percent of Latinx workers and 36% of Black workers report having no paid time off of any kind (BLS, 2019).

Since the 1930s, the unemployment insurance (UI) system has provided temporary, partial wage replacement benefits to people

Unemployment Assistance (PUA), which covers people who are not eligible for state UI benefits, including self-employed individuals and people with insufficient prior earnings. In addition to covering people who lose work due to COVID-19, PUA also covers people who are sick or caring for others with COVID-19 and who cannot work due to school closures. PUA is set to expire at the end of 2020. The CARES Act also created the Pandemic Unemployment Compensation (PUC) program, which provides an additional \$600 per week, through July 2020, to anyone receiving unemployment benefits, including PUA. The Act also provides an extra 13 weeks of benefits tacked onto the end of state UI benefits, expiring December 31, 2020.

Beyond leave and unemployment insurance, some jurisdictions have implemented innovative policies to support workers affected by COVID-19. For example, California created a \$125 million disaster relief fund providing \$500 grants, up to \$1,000 per household, for undocumented workers who are unable to access traditional unemployment benefits. Other states and localities have created similar disaster relief programs providing one-time payments, while Oregon implemented a \$20 million program providing weekly hardship payments to undocumented workers for a maximum of four weeks. Additionally, some localities like Los Angeles, San Jose, and San Francisco have adopted “right of recall” ordinances, which provide workers who have been laid off in industries heavily impacted by COVID-19 a right to return to their jobs once their employer reopens.

Assessment

Guaranteed Paid Leave for All Workers

Even before the coronavirus crisis hit, workers earning low wages, immigrants, people of color, workers with limited English proficiency, and LGBTQ+ individuals faced barriers to paid leave (Chang, 2015; Joshi, 2020). With workers now having less job security and even more caregiving responsibilities, the country is experiencing a caregiving and public health crisis that is hitting people with low incomes and intersectional identities especially hard.

The lack of universal, job-protected paid leave in the United States has long forced millions of workers to choose between their livelihood and their health. In the midst of a pandemic, the lack of these supports has even graver repercussions for our entire society. Without access to paid sick days and job-protected paid family and medical leave, many workers who are sick or exposed to the virus feel they have no choice but to go to work for fear of losing their jobs and income. This can spread infectious disease, including to other workers who are facing job instability, making tracing and containment nearly impossible. The Centers for Disease Control and Prevention estimated that during the H1N1 pandemic, seven million people were infected and 1,500 died because sick employees did not stay home.

Many of the paid leave laws that were on the books prior to COVID-19 are inadequate to meet workers’ needs during this pandemic. Among those with access to paid sick days, for example, the vast majority have nine days or fewer. But the COVID-19 incubation period can be as long as 14 days, and the disease can last much longer once symptoms begin.

Existing laws also do not cover the circumstances that many workers are facing in this crisis. For example, someone who is exposed to or infected with COVID-19 but remains asymptomatic may not qualify as having a serious illness or disability under the FMLA, the ADA, or analogous state laws. Likewise, existing leave laws may not offer protection to an employee who is not sick, but is vulnerable to severe complications because of their age or underlying conditions, or if they live with someone who is over 65 or otherwise vulnerable to complications.

Unfortunately, the FFCRA has not adequately addressed these gaps, and has exacerbated preexisting racial and socioeconomic disparities. According to the Center for American Progress, the law leaves up to 106 million workers without guaranteed protections (Glynn, 2020). At best less than half the private sector workforce has any guaranteed leave under the FFCRA, and at worst only 17% are covered (Glynn, 2020). Especially troubling, the law excludes millions of essential workers, who are predominantly people of color, immigrants, and women. Under DOL regulations that interpret the law’s exemptions extraordinarily broadly, everyone employed in the healthcare and emergency responder sectors can be excluded regardless of their job title. These exemptions are in addition to the millions who are automatically excluded because they work for employers with at least 500 people, including many essential grocery, agricultural, and retail workers. The vast majority of health care workers, including those working in nursing homes and providing care to elderly and at-risk individuals, may have no choice but to go to work sick or risk losing their job.

Moreover, FFCRA leave is only fully paid if taken for an employee’s own health and not for caregiving, which disproportionately harms women who do the bulk of family care. The Act also only provides two weeks to people who are sick with or caring for someone with COVID-19, even though the illness can last much longer.

Working parents, many of whom are sandwiched between caring for young children and older adults, are disproportionately harmed by inadequate leave protections. With the pandemic already lasting several months with no end in sight, 12 weeks of leave to care for children whose schools are closed is inadequate. Reports indicate that schools likely will open only part time, if at all, this fall, but the FFCRA does not allow intermittent leave unless the employer agrees, which means many parents will need to find alternative care or stay home and risk losing their job. Women are more likely to have been laid off, to have left, or to have considered leaving work to care for their families in the pandemic (Cassella & Mueller, 2020). Women of color are especially disadvantaged by school closures and inadequate leave policies, with potentially long-lasting detrimental effects on their families’ economic security, health, and wellbeing (Frye, 2020). Further, the FFCRA only provides extended leave to address care unavailability for children, not adults, which negatively impacts workers caring for older loved ones or those with disabilities.

Some states and localities have enacted paid leave laws that go beyond the FFCRA, but gaps remain. And the patchwork of federal, state, and local leave laws is confusing and difficult to navigate. Because employers pay benefits under the FFCRA, effective implementation requires extensive funding for outreach and

compliance assistance, as well as vigorous enforcement efforts to prevent retaliation against workers. With courts and labor agencies operating with limited capacity due to the pandemic, workers may face challenges enforcing their rights when employers violate the law.

Improved Access to Unemployment Insurance for All Workers

In a May 2020 survey, over 43% of adults said they or someone in their family had lost a job or income as a result of the economic fallout of COVID-19, with disproportionate losses among low-wage and Latinx workers (Acs & Karpman, 2020). The CARES Act has expanded access to UI for many nontraditional and low-income workers. The additional \$600 in weekly benefits under the PUC program has been shown to significantly lower poverty rates for people of color (DeParle, 2020). But unless Congress extends these supplemental benefits, they will expire at the end of July 2020, leaving millions without the ability to feed and house their families. A Congressional Budget Office report found that the cutoff of these benefits will disproportionately harm women and Black and Latinx workers.

The new benefits under the CARES Act also have added new layers of complexity, causing confusion about eligibility rules and how to navigate the system. For example, gig workers in some states could potentially be eligible for either regular UI or Pandemic Unemployment Assistance. In California, misclassified workers are entitled to regular UI but have to undergo a wage audit, leading to significant delays. Application and certification forms are confusing, and claimants may face overpayments and improper assessment of penalties for making “false statements” even if errors are made in good faith.

Although self-employed workers are newly eligible for pandemic unemployment benefits, those who have both wages and self-employment earnings are forced onto regular UI, and their benefit amounts do not account for their self-employment earnings, resulting in low benefit awards.

Further, as the economy reopens and people are called back to work, many will be working reduced schedules. But under offset rules in many states, earning even a fraction of one’s prior wages may make a worker completely ineligible for benefits. Others who are called back will feel unsafe returning but risk losing their benefits if they refuse to return to their jobs.

Administrative barriers, including inadequate staffing and outdated and under-resourced government systems have dramatically impeded access to benefits at a time when record numbers of people are needing assistance. State unemployment agencies have faced significant challenges in responding to this historic crisis. In a May survey, only 36.3% of adults whose families experienced job loss had received UI benefits in the previous 30 days (Acs & Karpman, 2020). Reports abound of people calling agencies dozens of times a day for days and weeks on end, without being able to reach anyone to address their questions. Claimants with limited English proficiency and without computers are especially harmed by insufficient access.

Perhaps the most significant gap in the current UI system is the categorical exclusion of undocumented workers. The U.S. workforce includes approximately 7.6 million undocumented workers, and research shows that they are facing disproportionately high rates of unemployment due to the pandemic. In California alone it is estimated that 357,867 undocumented workers have lost their jobs since the start of the pandemic (Flores & Padilla, 2020). While some states and localities have implemented disaster relief programs that provide undocumented individuals with one-time grants, these are woefully insufficient to meet the needs of workers and families who have gone months without any source of income. 🌞

Recommendations for Action

Federal government:

- Pass the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act to eliminate the employer exemptions to paid leave in the Families First Coronavirus Response Act (FFCRA) and to provide comprehensive emergency paid sick leave and paid family and medical leave, fully funded by the federal government.
- Enhance FFCRA enforcement by
 - o Allocating more funding to the Department of Labor (DOL) for FFCRA enforcement and outreach;
 - o Funding legal aid and community organizations to engage in outreach and enforcement;
 - o Requiring DOL to advise workers and employers to consult state and local laws that go above and beyond federal law to increase awareness of and compliance with all applicable leave protections;
 - o Requiring employers claiming exemptions under FFCRA to report and justify the exemptions to DOL.
- Pass the FAMILY Act to create a permanent paid family and medical leave social insurance program.
- Pass the Healthy Families Act to permanently guarantee employer-provided paid sick days to all workers.
- Extend unemployment benefits, including Pandemic Unemployment Compensation, for the duration of the pandemic.
- Extend unemployment benefits to undocumented workers.
- Revise unemployment insurance rules that penalize workers with both wages and self-employment earnings.
- Clarify that workers have the right to refuse unsafe work and remain eligible for unemployment benefits.

- Reform the Pandemic Unemployment Assistance program to allow waivers of overpayments.
- Expand access to the workshare program.

State governments:

- Appropriate and allocate state funds to create wage replacement programs for undocumented workers who have lost work or hours as a result of the COVID-19 pandemic.
- Pass supplemental paid leave laws that include
 - o Robust job protection, health insurance continuation, inclusive family definitions, and anti-retaliation provisions;
 - o Funding for enforcement and outreach, especially in languages beyond English;
 - o Ease certification requirements;
 - o Ensure that paid leave may be used for all coronavirus-related reasons, including the employee's own illness, school closures and unavailability of family care, and the vulnerability of the employee or someone in the home to complications of COVID-19.
- Require employers to provide reasonable caregiving accommodations, such as remote work and part-time schedules, to parents and caregivers.
- Increase benefit amounts and duration under permanent paid leave laws.
- Pass right of recall laws, giving workers who are laid off due to the pandemic a right to return to their jobs once their employers reopen.
- Reform earnings offset rules so that part-time workers can remain eligible for unemployment and paid family and medical leave benefits.
- To improve administration of unemployment and paid leave laws, state agencies should

- o Increase customer service staff and language access in unemployment and paid leave agencies; simplify and translate forms;
- o Ease standard for waiving overpayment of unemployment benefits, and require states to meet a heightened burden of proof before assessing a false statement penalty;
- o Issue administrative guidance clarifying that existing leave laws can be used for reasons related to COVID-19.

Local governments:

- Pass supplemental paid leave ordinances, with local enforcement power and funding for outreach and education.
- Pass right of recall ordinances.
- Fund medical-legal partnerships with public health departments to disseminate information about workplace rights at COVID-19 testing sites and via health clinics and hospitals.



About the Author

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References

- A Better Balance (ABB)(2020). Emergency Paid Leave Tracker: State, City, and County Developments. Retrieved July 27, 2020, from <https://www.abetterbalance.org/resources/emergencysickleavetracker/>
- Acs, G., & Karpman, M. (2020). Employment, Income, and Unemployment Insurance during the COVID-19 Pandemic. Retrieved July 5, 2020, from https://www.urban.org/sites/default/files/publication/102485/employment-income-and-unemployment-insurance-during-the-covid-19-pandemic_1.pdf
- Cassella, M. & Mueller, E. (June 25, 2020). A Lack of Child Care Is Keeping Women on Unemployment Rolls. Politico. Retrieved July 5, 2020, from <https://www.politico.com/news/2020/06/25/child-care-women-unemployment-339012>
- Chang, A. (2015). Paid Family Leave Market Research. Retrieved July 28, 2020 from California Employment Development Department. https://www.edd.ca.gov/Disability/pdf/Paid_Family_Leave_Market_Research_Report_2015.pdf
- DeParle, J. (2020). Vast Federal Aid Has Capped Rise in Poverty, Studies Find. New York Times. Retrieved July 5, 2020, from <https://www.nytimes.com/2020/06/21/us/politics/coronavirus-poverty.html>
- DeSilver, D. (Mar. 12, 2020). As Coronavirus Spreads, Which U.S. Workers Have Paid Sick Leave – And Which Don't? Retrieved July 5, 2020 from Pew Research Center, <https://www.pewresearch.org/fact-tank/2020/03/12/as-coronavirus-spreads-which-u-s-workers-have-paid-sick-leave-and-which-dont/>
- Flores, E. O., & Padilla, A. (2020). Policy Report: Persisting Joblessness Among Non-citizens during COVID-19. Retrieved July 5, 2020, from https://ssha.ucmerced.edu/sites/ssha.ucmerced.edu/files/documents/persisting_joblessness.pdf
- Frye, J. (2020). On the Frontlines at Work and at Home: The Disproportionate Economic Effects of the Coronavirus Pandemic on Women of Color. Retrieved July 6, 2020, from <https://www.americanprogress.org/issues/women/reports/2020/04/23/483846/frontlines-work-home/>
- Glynn, S. J. (Apr. 17, 2020). Coronavirus Paid Leave Exemptions Exclude Millions of Workers from Coverage. Retrieved July 5, 2020 from Center for American Progress, <https://www.americanprogress.org/issues/economy/news/2020/04/17/483287/coronavirus-paid-leave-exemptions-exclude-millions-workers-coverage/>
- Joshi, P., Baldiga, M., & Huber, R. (2020). Unequal Access to FMLA Leave Persists. Retrieved July 5, 2020, from <http://diversitydatakids.org/research-library/data-visualization/unequal-access-fmla-leave-persists>
- Livingston, G., & Thomas, D. (2019). Among 41 Countries, Only U.S. Lacks Paid Parental Leave. Retrieved July 5, 2020 from Pew Research Center, <https://www.pewresearch.org/fact-tank/2019/12/16/u-s-lacks-mandated-paid-parental-leave/>
- U.S. Bureau of Labor Statistics (BLS)(2020). Employee Benefits Survey, Leave Benefits: Access, Private Industry Workers Table 31, March 2019. Retrieved July 28, 2020, from <https://www.bls.gov/ncs/ebs/benefits/2019/ownership/private/table31a.pdf>
- U.S. Bureau of Labor Statistics (BLS)(2019). Access to and Use of Leave Summary (Table 1). Retrieved July 5, 2020, from <https://www.bls.gov/news.release/leave.t01.htm>
- World Policy Analysis Center (WPAC)(May 2020). Protecting Health During COVID-19 and Beyond: Where Does the U.S. Stand Compared to the Rest of the World on Paid Sick Leave?. Retrieved July 5, 2020 from <https://worldpolicycenter.org/sites/default/files/Fact%20Sheet%20-%20Protecting%20Health%20During%20COVID-19%20and%20Beyond%20-%2011May2020.pdf>

Using SNAP to Address Food Insecurity During the COVID-19 Pandemic

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SUMMARY. The United States Department of Agriculture’s most recent food insecurity data indicated that 37.2 million Americans were food insecure, meaning they did not have access to enough food to lead happy and healthy lives. Food insecurity is linked to a plethora of health issues including diabetes, hypertension, hyperlipidemia, asthma, poor mental health, birth defects, and impaired cognitive development in children. Like many public health challenges, there are severe racial disparities. White Americans experience food insecurity at a rate of 8.1%, while Black Americans and Latinx Americans experience it at rates of 21.2% and 16.2%, respectively. The COVID-19 pandemic has devastated the US economy with over 44 million Americans filing for unemployment by mid-June 2020. This economic devastation is expected to force an additional 17.1 million Americans into food insecurity. Federal and state governments are adapting key food security programs and implementing new interventions to meet these challenges. This Chapter will examine how the Supplemental Nutrition Assistance Program (SNAP), the nation’s largest nutrition program, is being leveraged during the pandemic. While key adaptations are being made to increase the effectiveness of these programs, additional measures are needed to protect vulnerable Americans during the pandemic. This Chapter’s recommendations include, but are not limited to: increasing the maximum SNAP allotment; withdrawing or repealing regulations that limit access to SNAP; repealing the national ban that prohibits individuals with drug felonies from accessing SNAP; making online SNAP utilization available in all states; and providing for the delivery of online SNAP orders with no additional cost to the beneficiary.

Introduction

Prior to the pandemic, 37.2 million Americans were food insecure, meaning they did not have access to enough food to lead happy and healthy lives (Coleman-Jensen et al., 2019). Food insecurity is linked to a plethora of health issues, including diabetes, hypertension, hyperlipidemia, asthma, poor mental health, birth defects, and impaired cognitive development in children (Gundersen & Ziliak, 2015). Like many public health challenges, there are severe racial disparities. White Americans experience food insecurity at a rate of 8.1%, while Black Americans and Latinx Americans experience it at rates of 21.2% and 16.2% respectively (Coleman-Jensen et al., 2019). The COVID-19 pandemic has devastated the U.S. economy with over 44 million Americans filing for unemployment by mid-June 2020 (Tappe & Luhby, 2020). This economic devastation is expected to force an additional 17.1 million Americans into food insecurity (Feeding America, 2020). As a result, the government is leveraging the Supplemental Nutrition Assistance Program (SNAP) to meet the needs of the food insecure. This Chapter will evaluate efforts to modify SNAP with measures

that (1) increase the value of benefits provided, (2) increase the number of individuals eligible for the program, and (3) incorporate social distancing into the administration of SNAP.

Supplemental Nutrition Assistance Program

SNAP is the largest nutrition program in the United States. Prior to the pandemic, approximately 37 million people relied on this program to help meet their nutrition needs (USDA Data Table, 2020). SNAP provides eligible low-income households with a monthly allotment to purchase food. The federal government provides 100% of funding for this allotment. The allotment benefits are placed on an Electronic Benefits Transfer (EBT) card, which functions like a debit card and can be used at certified vendors. The value of a household’s allotment is based on the income of the household and the number of individuals in the household. In addition to providing the funding for the benefit, the federal government establishes many of the baseline requirements for the program, while each state is responsible for administering the program within its jurisdiction.

In addition, to helping feed Americans who are food insecure, the SNAP program is an excellent tool for stimulating the economy during difficult times. A recent US Department of Agriculture (USDA) study indicates that during a weak economy, every dollar of a new SNAP benefit creates an additional \$1.54 in gross domestic product (Canning & Mentzer Morrison, 2019). The study also found that additional SNAP funding supports job growth: an additional \$1 billion in SNAP funding was projected to support 13,560 jobs across a broad spectrum of sectors including agriculture, transportation, manufacturing, food services, and health care. This ability to generate additional economic activity makes the SNAP program a critical tool during the COVID-19 pandemic.

Increasing the Value of the SNAP Allotment

Emergency Allotments. To better combat food insecurity during the pandemic, the value of the SNAP allotment must be increased to provide households more money for food. The Families First Coronavirus Response Act (FFCRA) of 2020 utilized this intervention by authorizing emergency allotments for the SNAP program. FFCRA allows states to request from the Secretary of Agriculture an increase in the allotments provided to SNAP households. The increase in a household's allotment cannot exceed the maximum monthly allotment for a household of its size. As mentioned above, the value of a household's allotment is based on their income and the number of individuals in the household. For example, in 2020 a family of four can receive up to \$646 in SNAP allotment depending on the income of the household (USDA SNAP Eligibility, 2020). With emergency allotments, states can request the maximum allotment for a household regardless of the income of that household.

While emergency allotments help support many Americans during the pandemic, this intervention ignores households with the lowest incomes because they already receive the maximum allotment. These households represent approximately 40% of SNAP households (Rosenbaum et al., 2020). This oversight is exacerbated by the sad reality that even under normal conditions, SNAP allotments are inadequate. In 2013, the Institute of Medicine and the National Research Council conducted a study that determined SNAP allotments failed to provide for a minimally adequate diet for several reasons, including the failure of the benefit to keep up with inflation and to accurately account for the cost-time trade-offs in obtaining a healthy diet. In addition, in a 2012 study, the Food Research Action Center (FRAC) revealed that SNAP allotments are insufficient because they are based on the USDA's flawed Thrifty Food Plan (TFP). The TFP is one of the USDA's four model meal plans and is meant to provide a healthy diet for minimal cost. FRAC found that the TFP provided a faulty base for SNAP allotments because it assumes impractical lists of foods; lacks the variety called for in the dietary guidelines; ignores special dietary needs; unrealistically assumes food availability and affordability, and adequate transportation to food retailers; and exceeds the value of SNAP benefits in many parts of the country.

Increase Maximum SNAP Allotment. To address the shortcomings of the emergency allotment provision, the federal government must pass legislation that will increase the value of the maximum

allotment to help the most vulnerable families that receive no additional support from the emergency allotment provision. In addition, this measure will increase allotments for most SNAP households because the maximum allotment is the basis for most benefit calculations. This intervention proved successful during the Great Recession. The American Recovery and Reinvestment Act (ARRA) of 2009 temporarily increased the maximum SNAP allotment by 13.6%, which resulted in improved food security, improved health, decreased health care costs, and promoted economic growth (Hartline-Grafton et al., 2019). With regards to economic growth, the increased allotments generated an additional \$40 billion in economic stimulus beyond the funds dedicated to the SNAP program (Rosenbaum et al., 2020). As a result of the general inadequacy of the SNAP allotments, the public's health would benefit from a permanent increase in the SNAP allotment. However, given the political reality, a temporary increase in benefits that is linked to the duration of pandemic's economic impact is a more feasible.

There are two simple ways this increase could be accomplished. First, federal legislation could increase the maximum allotment by a certain percentage as was done by the ARRA. Currently, the Health and Economic Recovery Omnibus Emergency Solutions (HEROES) Act proposes a temporary 15% increase in the value of the maximum SNAP allotment, which sunsets on September 30, 2021. Second, allotments could be increased through federal legislation that requires the calculation of SNAP allotments to use the USDA's Low-Cost Food Plan (LFP) rather than the Thrifty Food Plan (TFP). The LFP is the USDA's second-most frugal plan and is often used to calculate alimony and child support (Carlson et al., 2007). This modification was proposed in the Closing the Meal Gap Act of 2019, which has been in a subcommittee since March 15, 2019. If this approach is used, it would increase the maximum value of SNAP allotments by more than 15%. For example, in the most recent food plan report, a household with two adults under the age of 51 receives \$405.30 under the TFP and \$520 under the LFP (USDA, Food Plans, 2020). This is a 28.3% difference in the value of the plans. While either of these approaches would be an improvement, linking the benefit calculation to the LFP would provide greater food security and a larger economic stimulus because of its larger investment in SNAP.

The HEROES Act's proposed increase to the SNAP allotment is a positive step forward, but its arbitrary sunset date, September 30, 2021, undermines its effectiveness. The duration of any temporary increase should be linked to an economic metric that reflects a decreased need for government support. The Center of Budget and Policy Priorities recommends terminating the increase when there is a decrease in the three-month unemployment rate for two straight months that results in an unemployment rate within 1.5% of the pre-pandemic level (Rosenbaum et al., 2020).

Increase Minimum SNAP Allotment. The value of the minimum SNAP allotment must also be increased for smaller households. Currently, SNAP households composed of one or two people are guaranteed a minimum allotment of \$16 per month. Approximately 1.8 million households receive the minimum benefit, the majority of which include elderly individuals. The suggested increase of

15% to the maximum allotment would only increase the allotments of these households by \$2 (to \$18 per month) (Rosenbaum et al., 2020). To provide meaningful support to these households, the federal government should increase the minimum benefit to \$30 per month. The HEROES Act proposes this approach. However, if the federal government is unwilling to provide this support, state governments should pass legislation that supplements the minimum allotment. In fact, some states have already taken this type of action. For example, Maryland increased the value of the minimum allotment to \$30 dollars for households with an individual who is at least 62 years old. While increasing the minimum allotment may seem like a moot point with the emergency allotment in place, it is unclear how long the emergency allotment provision will continue. Increasing the minimum allotment ensures that 1.8 million households receive more viable resources to fight food insecurity.

Increasing the Number of Individuals Eligible for SNAP

Able-Bodied Adult Without Dependents (ABAWD) Requirement.

During the pandemic, SNAP must be available to those who need it. The FFCRA made a critical change to the ABAWD requirement, which requires individuals between the ages of 18-49, who can work and do not have dependents, to meet special work requirements to receive more than three months of SNAP benefits in a three-year period.

FFRCRA provides a waiver of the ABAWD work requirement from April 1, 2020 through one month after the termination of the federal public health emergency declaration for COVID-19. This waiver is logical given the tremendous downturn in the economy. However, the duration of the waiver may not match the strength of the economy and the availability of jobs. If the public health emergency declaration is ended before the economy has recovered, vulnerable Americans will be left without the support of SNAP. To prevent this possibility, federal legislation is needed to link the sunset provision to an economic recovery metric. Again, the unemployment metric proposed early in the Chapter could be applied to the waiver.

While ensuring that the ABAWD waiver remains in place until the economy recovers is critical, other steps must be taken to protect access to SNAP. The USDA recently finalized regulations (84 Fed. Reg. 66,792, 2019) modifying the ABAWD requirement so that it is more restrictive. Specifically, the regulations make it harder for states to qualify for waivers based on poor economic conditions and lessen a state's ability to offer monthly individual exemptions to struggling ABAWDs. The regulations have been challenged in court and a final decision of validity of the waiver restrictions is pending ("District of Columbia v. USDA", 2020). Regardless of the case's outcome, the contested ABAWD regulations must be repealed so states have the flexibility needed to support vulnerable people.

Categorical Eligibility. In addition, proposed changes to SNAP's categorical eligibility provision must be withdrawn. To receive SNAP benefits, a household must meet specific income guidelines or be categorically eligible. Categorical eligibility allows households to automatically qualify for SNAP if they receive benefits from government programs (e.g., Temporary Assistance

for Needy Families) that check income and assets to confer eligibility. The USDA has proposed (84 Fed. Reg. 35,570, 2019) changing the government benefits that will confer categorical eligibility for SNAP. According to the 2019 Revision of Categorical Eligibility in SNAP Regulatory Impact Analysis, 3.1 million people are expected to lose SNAP benefits because of the proposed changes. These changes also impact school lunch and breakfast program eligibility. Children automatically qualify for free school meals if their household participates in SNAP. If the proposed regulations are finalized, hundreds of thousands of children will lose access to free school meals (FNS, 2019). It would be devastating if these regulations were finalized during the pandemic, though they should be withdrawn regardless of the pandemic as they degrade the nation's ability to support its people.

Ban On Individuals With Drug Felony Convictions. Finally, the lifetime ban on SNAP benefits for individuals with a felony drug conviction, created by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), must be repealed. This ban disproportionately impacts people of color and women, undermines the food security of families, and creates barriers to reintegration. PRWORA does have a provision that allows states to opt out of the ban or modify it through state legislation. Currently, only South Carolina has left the full ban in place, whereas 22 states and the District of Columbia have completely opted out of the ban and 27 states have modified the ban so that a qualifying person with a felony drug conviction is still eligible for SNAP. The state modifications range from requiring drug testing to receive benefits to only banning individuals with multiple drug felonies (Payne et al., 2020). Unlike the ABAWD requirement, there is no waiver of the felony ban during the pandemic. As a result, an already vulnerable population is subject to an even greater risk of food insecurity. Regardless of the pandemic, it is unconscionable to continue this ban in any format. The federal government must repeal the ban and, if it is unwilling to do so, states must completely opt out of it.

Incorporating Social Distancing into the Administration of SNAP

FFRCRA authorized the USDA to adjust issuance methods and application requirements for the SNAP program to encourage social distancing. First, upon the request of a state, the USDA can waive the face-to-face interview requirement for SNAP certification and recertification. This waiver, authorized by FFCRA, allows states to gather certification information through alternative means such as telephone interviews.

The Online SNAP Pilot. Second, the USDA is rapidly expanding its SNAP Online Purchasing Pilot. The 2014 Farm Bill tasked the USDA with creating a pilot program to evaluate the use of SNAP benefits online. Originally, the pilot focused on increasing access to food for those with limited access to food resources because of geography or limited mobility. However, this program is an excellent tool for social distancing. Individuals who receive SNAP no longer need to physically go to the grocery store. When the pilot started in April 2019, New York was the only participating state. However, the need for social distancing during the pandemic led the USDA to rapidly expand the pilot. Currently, the pilot is operational in 39 states and

the District of Columbia, with four additional states approved but not yet operational (USDA, 2020). This initial growth of the online pilot is critical, but the USDA, state governments, and food retailers must expand the pilot to every state. Not only does this program promote social distancing, it increases access in food deserts and for individuals who cannot physically access resources due to mobility or transportation challenges.

Delivery For Online SNAP Program. While the expansion of the online pilot is an important measure, there is a legal barrier to ensuring this program is effective. SNAP benefits cannot be used for delivery fees associated with the online food purchases (USDA, 2020). This undercuts the benefits of the pilot by placing the financial burden of delivery fees on the SNAP household.

Federal legislation should be passed requiring food retailers participating in the program to offer free delivery to SNAP beneficiaries under certain conditions. For example, if a retailer offers free delivery to non-SNAP customers when they purchase a certain dollar amount of food, they must also offer this service to SNAP customers. The proposed \$30 minimum allotment could serve as a baseline measure for free delivery, which may be lower than some retailers' current trigger point. This approach places the burden on the retailers to incorporate the additional delivery costs and may discourage smaller vendors from participating in the online SNAP program. However, Amazon and Walmart are the major retail participants in the pilot and have operations in every state. Given the potential SNAP spending generated by the online program and the economies of scale these massive retailers control, they are in an excellent position to sustain additional expenses associated with delivery services to SNAP beneficiaries. 🌱

Recommendations for Action

Federal government

Congress should:

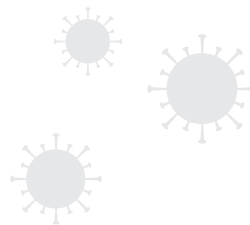
- Temporarily increase the maximum value of the SNAP allotment by 15% or by linking benefit calculations to the Low-Cost Food plan. The duration of this allotment increase should be linked to an economic recovery metric;
- Increase the minimum value of a SNAP allotment from \$16 to \$30;
- Link the duration of the temporary Able-Bodied Adult Without Dependents Requirement (ABAWD) waiver to the nation's economic recovery, rather than the termination of the public health emergency declaration;
- Repeal legislation that bans individuals with felony drug convictions from participating in the SNAP program (21 U.S.C. § 862a);
- Pass legislation that makes the online SNAP pilot a permanent program;
- Pass legislation requiring food retailers participating in the online SNAP program to offer free delivery under certain conditions.

The Department of Agriculture should:

- Rescind recently promulgated regulations (84 Fed. Reg. 66,782) that restrict ABAWD access to SNAP;
- Rescind regulations (84 Fed. Reg. 35,570) that decrease access to nutrition programs by restricting SNAP categorical eligibility;
- Work with states and food retailers to expand the online SNAP pilot to all 50 states.

State governments:

- If the federal government fails to repeal the SNAP ban on individuals with felony drug convictions, pass legislation that completely opts out of the SNAP felony ban.
- If the federal government fails to increase the minimum SNAP allotment, pass legislation to increase the minimum value of SNAP allotment within the state. This requires allocation of state funds to supplement the federal benefit.



About the Author

Mathew Swinburne, JD, is the Associate Director for the Network for Public Health Law-Eastern Region. His works focuses on issues of food safety and security, injury prevention, social justice, and cannabis regulation. He is also an adjunct professor for the University of Maryland, College Park, where he teaches Health Law and Ethics.

References

- Canning, P., & Mentzer Morrison, R. (2019) Quantifying the Impact of SNAP Benefits on the U.S. Economy and Jobs. Retrieved July 15, 2020 from US Department of Agriculture, <https://www.ers.usda.gov/amber-waves/2019/july/quantifying-the-impact-of-snap-benefits-on-the-us-economy-and-jobs/>
- Carlson, A., Lino, M., & Fungwe, T. (2007). The Low-Cost, Moderate-Cost, and Liberal Food Plans, 2007, (CNPP-20). Retrieved July 15, 2020 from US Department of Agriculture, https://fns-prod.azureedge.net/sites/default/files/usda_food_plans_cost_of_food/FoodPlans2007AdminReport.pdf
- Coleman-Jensen, A., Rabbitt, M. P., Gregory, C. A., & Singh, A. (2019). Household Food Security in the United States in 2018 (ERR-270). Retrieved July 15, 2020 from US Department of Agriculture, Economic Research Service, <https://www.ers.usda.gov/webdocs/publications/94849/err-270.pdf?v=2815.3>
- Feeding America (2020). The Impact of the Coronavirus on Food Insecurity. Retrieved July 15, 2020, from https://www.feedingamerica.org/sites/default/files/2020-04/Brief_Impact%20of%20Covid%20on%20Food%20Insecurity%204.22%20%2800%29.pdf
- Food and Nutritional Service (FNS)(2019). Proposed Rule: Revision of Categorical Eligibility in the Supplemental Nutrition Assistance Program (RIN 0584-AE62) – Potential impacts on Participants in the National School Lunch Program and School Breakfast Program. Retrieved July 15, 2020, from <https://www.regulations.gov/document?D=FNS-2018-0037-16046>
- Gundersen, C., & Ziliak, J. P. (2015). Food Insecurity and Health Outcomes. *Health Affairs*, 34(11), 1830-1839.
- Hartline-Grafton, H., Weill, J., & Vollinger, E. (2019) Initiatives to Make SNAP Benefits More Adequate Significantly Improve Food Security, Nutrition, and Health. Retrieved July 15, 2020 from Food Research and Action Center, <https://frac.org/wp-content/uploads/snap-initiatives-to-make-snap-benefits-more-adequate.pdf>
- Payne, H., Morrow, M., Gbemudu, A., & Horine, D. (2020). 50-State Survey: SNAP Ban of Persons with Drug Felony Convictions. Retrieved July 15, 2020 from the Network for Public Health Law, <https://www.networkforphl.org/resources/effects-of-denial-of-snap-benefits-on-convicted-drug-felons/>
- Rosenbaum, D., Dean, S., & Neuberger, Z. (2020). The Case for Boosting SNAP Benefits in Next Major Economic Response Package. Retrieved July 15, 2020 from Center on Budget and Policy Priority, <https://www.cbpp.org/research/food-assistance/the-case-for-boosting-snap-benefits-in-next-major-economic-response-package>.
- Tappe, A., & Luhby, T. (2020), Another 1.5 million Americans filed for first-time unemployment benefits last week. *CNN*. Retrieved July 15, 2020, from <https://www.cnn.com/2020/06/11/economy/unemployment-benefits-coronavirus/index.html>.
- United States Department of Agriculture (USDA)(2020). FNS Launches the Online Purchasing Pilot. Retrieved July 15, 2020, from <https://www.fns.usda.gov/snap/online-purchasing-pilot>
- United States Department of Agriculture (USDA Data Table)(2020). National and/or State Level Monthly and/or Annual Data. Retrieved July 15, 2020, from <https://fns-prod.azureedge.net/sites/default/files/resource-files/34SNAPmonthly-6.pdf>
- United States Department of Agriculture (USDA Food Plans)(2020). Official USDA Food Plans: Cost of Food at Home at Four Levels, U.S. Average, May 2020. Retrieved July 15, 2020, from <https://fns-prod.azureedge.net/sites/default/files/media/file/CostofFoodMay2020.pdf>
- United States Department of Agriculture (USDA SNAP Eligibility)(2020). SNAP Eligibility. Retrieved July 15, 2020, from <https://www.fns.usda.gov/snap/recipient/eligibility>

The background is a solid teal color. A large, semi-circular graphic is positioned on the left side, divided into two horizontal sections: a lighter teal top half and a red bottom half. The text is placed within the red section of this graphic.

PART 6

**Taking on Disparities and
Protecting Equal Rights**

Summary of Recommendations for Taking on Disparities and Protecting Equal Rights

Compiled and edited by the Editorial Committee

The editors asked the authors to provide their best recommendations for legal action in response to COVID-19. Recommendations for *Taking on Disparities and Protecting Equal Rights* address persistent equity gaps that have been exposed by the pandemic. These recommendations include both calls for urgent action now, as well as longer term changes that reflect the way the pandemic has highlighted deeper problems in American law and policy. We have organized the recommendations into federal, state, local and Tribal guidance.

Each recommendation is referenced back to its author(s). Please refer to specific chapters for a complete list of recommendations on a particular topic.

Action at the Federal Level

- Congress and the White House should jointly convene an independent commission or National Academies committee to examine the causes of racial and ethnic disparities in COVID-19 infections and associated harms (Anderson and Burris, *Is Law Working*)
- Congress should dedicate and increase resources to federal agencies to coordinate with civil rights and public health organizations to inform, enforce, and further civil rights protections in the COVID-19 response (Harris and Pamukcu, *Civil Rights*)
- Agencies should develop guidance for the use of “targeted universalism” (combining universal objectives and programs with targeted corrective justice projects) as a policy and planning frame in order to benefit all populations while specifically addressing the harms of racism (Harris and Pamukcu, *Civil Rights*)
- To promote equitable access to broadband internet service during COVID-19 and beyond,
 - o Congress should
 - Amend Title 47 of the United States Code to classify broadband as a telecommunications service, or otherwise provide needed oversight that could help increase competition and eliminate the digital divide
 - Amend Title 47 of the United States Code to prohibit state preemption of local broadband markets and decision-making
 - Enact federal legislation requiring broadband infrastructure to be built in conjunction with other government funded construction projects
 - Appropriate additional funding for libraries, community anchor institutions, and schools for the purchase of mobile hotspots that can be loaned to individuals or used to benefit underserved and unserved communities
 - o The FCC should
 - Issue an order authorizing the use of E-rate funding to support offsite broadband access on school buses, at community anchor institutions, and at student homes; and waiving the E-rate funding penalty for schools that provide off-site broadband services. FCC should revise its regulations, 47 C.F.R. § 54.500 et seq, to codify these changes and expand the E-Rate program
 - Revise its Lifeline regulations, at 47 C.F.R. § 54.400 et seq., to increase the amount of the Lifeline discount
 - Work with other federal agencies to bundle Lifeline enrollment with enrollment in other federal programs
 - Collect data on affordability and availability of broadband service throughout the United States, including demographic data such as language, race and ethnicity (Lawton, *COVID-19*)
 - o Congress by statute or the Federal Communications Commission by rule should prohibit states from preempting local governments from building or expanding access to municipal broadband (Haddow et al, *Preemption*)
- To protect incarcerated persons, staff and their communities,
 - o The Federal Bureau of Prisons should:
 - Continue decarceration efforts while ensuring reentry services are expanded accordingly
 - Restore that gave cell phones to those who cannot afford a phone line (1) for communication with family, employers, and social services and (2) as a way to check in with parole/probation, register for benefits, contact social workers, and schedule appointments with health care
 - Ensure access to shelter upon release, including providing temporary housing (e.g., hotels) to individuals who need assistance or a safe space to quarantine post-release

- Conduct frequent (daily or weekly) COVID-19 screenings on all staff and individuals incarcerated in federal facilities
 - o The Department of Health and Human Services should continue to encourage states to use emergency 1135 waivers, which allow states to use Medicaid funds for housing and moving expenses
 - o Congress should
 - Eliminate the “inmate exclusion” in Medicare and Medicaid, opening the door for the use of federal health dollars in correctional settings
 - Change laws, including controlled substances and other statutes criminalizing health and economic vulnerability, to shrink the footprint of the criminal legal system (Bresler and Beletsky, COVID-19)
- To assure that COVID-19 response respects the rights and well-being of people with disabilities, federal agencies should provide clear, ongoing legal guidance. Specifically:
 - o The HHS Office for Civil Rights should continue to enforce and provide COVID-specific guidance on the requirements of the Americans with Disabilities Act, Rehabilitation Act, and Section 1557 of the ACA for health care providers, institutions, and systems regarding medical allocation policies, hospital visitor policies, and other policies that impact care for people with disabilities
 - o Following the example of the Equal Employment Opportunity’s guidance for private employers, the Department of Justice should provide similar guidance on the requirements of the ADA and Rehabilitation Act in COVID-related policies adopted by state, local, and retail and other business entities, including mask-wearing policies (Pendo, Protecting the Rights of People with Disabilities; see also Gable, Crisis)
- To minimize the risk of the spread of COVID-19 to immigrants, staff, communities and globally,
 - o ICE should
 - Declare that it will not enforce immigration laws within any health care facility, and that it will not use any information obtained from health or public health workers, including from contact tracers This declaration should be widely messaged, in multiple languages, to immigrant communities
 - Suspend immigration raids during the pandemic, except where they are necessary to prevent an imminent risk to public safety A pandemic is not the time to time to add to fear and distrust in immigrant communities
 - Further depopulate immigration detention facilities, holding only immigrants who pose an immediate risk to public safety ICE should ensure that detainees who remain receive language-appropriate health information, adequate health care, and the means to practice good hygiene and social distancing (Parmet, Immigration)
 - o USCIS, or Congress if USCIS does not act, should repeal the public charge rule, or at least, suspend it for the duration of the pandemic (Parmet, Immigration)
 - o Congress should extend unemployment benefits to undocumented workers (Terman, Protecting Workers)
- Congress should ensure that organizations that provide direct relief and services, including LGBT organizations, are eligible for funding under CARES Act and future emergency support measures (Konnoth, Supporting LGBT Communities)
- Consistent with the Supreme Court’s recent decision in *Bostock v Clayton County*,
 - o HHS should issue a regulation affirming that Section 1557 of the Affordable Care Act prohibits discrimination based on sexual orientation and gender identity
 - o HUD should withdraw its proposed rule reversing the Obama Administration’s Equal Access Rule, which required that Housing and Urban Department programs, including certain shelters, were open to all eligible families and individuals “without regard to actual or perceived sexual orientation, gender identity, or marital status” (Konnoth, Supporting LGBT Communities)
- HHS, DOJ, and other relevant agencies should clarify that the Religious Freedom Restoration Act and other religion-related protections do not justify discrimination against LGBT individuals (Konnoth, Supporting LGBT Communities)
- FDA should remove all vestiges of its ban on blood donation by men who have sex with men from its blood donation guidance, so that the LGBT community is not excluded from assisting in the COVID-19 relief effort (Konnoth, Supporting LGBT Communities)

Action at the State Level

- To sharpen a focus on equity and instigate action in state government, governors should
 - o Instruct public health officials to incorporate equity considerations and address the needs of vulnerable populations in all COVID-19 orders, policies and programs (Jacobson et al, Executive Decision Making)
 - Population measures to increase physical distance must be complemented by risk reduction measures to support people who are required by their jobs or economic necessity to work, travel on public transportation, and spend time in congregate settings
 - These may include provision of high-quality PPE appropriate to the physical situation, hazard pay, paid sick leave, health insurance, and redesign of work procedures and settings (Anderson and Burris, Is Law Working)
 - o Require and support agencies to develop guidance on the use “targeted universalism” (combining universal objectives and programs with targeted corrective justice projects) as a policy and planning frame in order to benefit all populations

- while specifically addressing the harms of racism (Harris and Pamukcu, Civil Rights)
- To increase community involvement and voice,
 - o Legislators and governors should realign budgets around preventive health and provide community budgeting participation and oversight
 - o Legislators and agencies should provide funding to supporting community-based organizations working to address the social determinants of health, the racial health gap, and/or anti-discrimination efforts (Harris and Pamukcu, Civil Rights)
- To promote equitable access to broadband internet service during COVID-19 and beyond,
 - o Legislators and agencies should adopt laws and regulations requiring broadband infrastructure to be built in conjunction with other government construction projects.
 - o Legislators should adopt statewide connectivity goals and deadlines (Lawton, COVID-19)
 - o State legislatures should appropriate funds and enact laws to subsidize high-speed, broadband internet for residences and alternative housing, such as homeless shelters or hotels and motels used to provide shelter for those experiencing homelessness (Anderson, A Pandemic)
- To reduce the unhealth effects of incarceration on prisoners, families and communities during COVID-19 and beyond,
 - o State correctional officials should
 - Expand COVID-19 testing of individuals and correctional officers in carceral institutions
 - Ensure transportation, provide financial assistance, and provide temporary ID cards to those without valid ID upon release
 - o Legislators and appropriate agencies should
 - Change statutes, regulations, and institutional policies to ensure individuals are not barred from seeking public assistance for housing and other needs due to their record
 - Change statutes, regulations, and institutional policies to relax conditions of probation and parole that mandate obtaining employment, substance use treatment, housing, or continuing education
 - o Legislators should mandate and fund the
 - Virtual job counseling and access to online classes for those reentering (and technology resources for those who can no longer access places with publicly available resources)
 - Expanded reentry services and virtual capacity to ensure the continuation of such services
 - Services to reduce COVID-19 spread and other health harms post-incarceration, including access to shelter upon release, medications during and after incarceration, testing for COVID-19 upon release, and again two weeks after, provision of naloxone (the opioid overdose reversal drug) to individuals with SUD, and assistance with re-enrolling in Medicaid to those who qualify
- o Legislators should repeal criminal record bans for health care profession licensing for people otherwise qualified and not a risk (Bresler and Beletsky, COVID-19)
- To assure that COVID-19 response respects the rights and well-being of people with disabilities, State agencies should
 - o Enforce and provide COVID-specific guidance on the requirements of state laws that prohibit discrimination based on disability
 - o Review and revise state and local policies related to COVID-19, including medical allocation policies, hospital visitor policies, and mask-wearing policies, to ensure that they comply with requirements of federal and state disability rights law (Pendo, Protecting the Rights of People with Disabilities; see also Krueger, Mental Health)
- To ensure LGBT individuals have access to essential services, state attorneys general should clarify that sex discrimination prohibitions in public accommodation discrimination, present in all 50 states, also prohibit discrimination based on sexual orientation and gender identity (Konnoth, Supporting LGBT Communities)
- To ensure that contract tracing apps and processes do not reflect bias or infringe upon civil liberties and human rights, state governments by legislation or agency rule should ensure that as implemented:
 - o Applications neither (1) intentionally nor disparately burden folks on the basis of race, ethnicity, nationality, sex, religion, immigration status, LGBTQ+ status, or disability, nor (2) document information that implicates users' civil liberties or human rights
 - o Health authorities provide no-cost cellular phones and data packages to individuals who wish to participate but do not have the resources to obtain the underlying technology, devices, and data plans
 - o Health authorities incorporate the use of traditional contact tracers with local connections to vulnerable communities rather than solely rely on automated surveillance to ensure the inclusion of individuals who do not have access to smartphone technology and/or otherwise distrust digital surveillance (Oliva, Surveillance)

Action at the Local Level

- Local governments should
 - o Realign government budgets around preventive health and provide community budgeting participation and oversight
 - o Recognize and address racism as an institutional and systemic issue, by, for example, issuing a declaration characterizing racism as a public health crisis

- o Use “targeted universalism” (combining universal objectives and programs with targeted corrective justice projects) as a policy and planning frame in order to benefit all populations while specifically addressing the harms of racism (Harris and Pamukcu, Civil Rights; see also Krueger, Mental Health)
- o Actively enforce anti-discrimination laws and provide proactive education on antidiscrimination requirements (Krueger, Mental Health)
- To promote equitable access to broadband internet service during COVID-19 and beyond, cities and counties should
 - o require broadband infrastructure to be built in conjunction with other government construction projects
 - o provide free community-wide wireless
 - o promote competition by supporting local public utilities and cooperatives
 - o work with schools, community anchor institutions, and public health departments should develop public private partnerships to support broadband connectivity
 - o develop community wide connectivity goals (Lawton, COVID-19)
- To reduce the unhealthy effects of incarceration on prisoners, families and communities during COVID-19 and beyond,
 - o City and county jail officials should
 - Expand COVID-19 testing of individuals and correctional officers in carceral institutions
 - Ensure transportation upon and provide financial assistance upon release
 - o Local governments should mandate and fund
 - Virtual job counseling and access to online classes for those reentering (and technology resources for those who can no longer access places with publicly available resources)
 - Expanded reentry services and virtual capacity to ensure the continuation of such services
 - Services to reduce COVID-19 spread and other health harms post-incarceration, including access to shelter upon release, medications during and after incarceration, testing for COVID-19 upon release, and again two weeks after, provision of naloxone (the opioid overdose reversal drug) to individuals with SUD, and assistance with re-enrolling in Medicaid to those who qualify
- o Legislators should enact “ban the box” ordinances prohibiting the check box that asks if applicants have a criminal record in hiring applications (Bresler and Beletsky, COVID-19)
- Local governments should review and revise local policies related to COVID-19, including mask-wearing policies, to ensure that they comply with requirements of federal disability rights law (Pendo, Protecting the Rights of People with Disabilities)

Action at the Tribal Level

- Tribal governments should instruct public health officials to incorporate equity considerations and address the needs of vulnerable populations in all COVID-19 orders, policies and programs (See Jacobson et al, Executive Decision Making)

COVID-19 Illustrates Need to Close the Digital Divide

Betsy Lawton, JD, Network for Public Health Law–Northern Region

SUMMARY. The COVID-19 pandemic has heightened the need for internet connectedness – school and work closures and social distancing measures to slow the spread of COVID-19 require individuals to rely even more heavily on internet access to participate in telehealth programs, distance learning, and job opportunities. Yet, there remains a large digital divide in the United States, with many households lacking access to reliable broadband services. This digital divide has long been a factor limiting the achievement of public health goals for individuals that lack essential broadband infrastructure and COVID-19 response efforts have further limited internet access for those that rely on public internet access points such as public libraries. This Chapter will explore law and policy opportunities to reduce the digital divide and the resulting public health consequences flowing from the digital divide.

Introduction

One goal of the Federal Communications Commission’s (FCC) 2010 Connecting America: The National Broadband Plan was that “[e]very American should have affordable access to robust broadband service and the means and skills to subscribe if they so choose.” Access to broadband is essential to parity in public health, yet many households in the United States lack consistent access to broadband services due to lack of broadband infrastructure and the high cost of service (Crock Bauerly et al., 2019; Tomer et al., 2020). While the digital divide is shrinking, there remain large pockets of rural and urban Americans that do not have consistent access to broadband – this creates disparities in educational opportunities, job prospects, and telehealth availability (Tomer et al., 2020). As the FCC noted in a 2015 rulemaking order:

Today, broadband is essential to participate in society. Disconnected consumers, which are disproportionately low-income consumers, are at an increasing disadvantage as institutions and schools, and even government agencies, require Internet access for full participation in key facets of society.... [S]tudent access to the Internet has become a necessity, not a luxury.

Because broadband availability so greatly influences the social determinants of health, it is sometimes called a super-determinant of health (Crock Bauerly et al., 2019).

The majority of disconnected households are in urban areas, but rural rates of broadband adoption are lower, 79%, when compared to 84% adoption rates in urban areas (Tomer et al., 2020). Even where infrastructure is accessible, some 23.7% of Americans have only one option for purchasing broadband service (Kruger & Gilroy, 2019). Disconnected households are more prevalent in majority

Black neighborhoods, where adoption rates are only 67.4%, compared with much higher adoption rates, 83.7%, in majority-white tracts (Tomer et al., 2020). For individuals living on Tribal lands, 32% have no access to any fixed broadband with reliable speeds, and 36.1% only have access to reliable service from one provider (Kruger & Gilroy, 2019). These broadband disparities can exacerbate economic, educational, and health inequities. For more detailed information related to disparities in access to telehealth services, see Chapter 16.

Educational inequities tied to disparities in broadband access – sometimes called the homework gap – impact the ability of millions of children to meaningfully engage in schoolwork. The COVID-19 pandemic has contributed to the severity of the homework gap, particularly in Black, Native American, Hispanic, and low-income communities (Alliance for Excellent Education, 2020). School closures intended to mitigate the spread of COVID-19, are likely to worsen educational disparities, leaving children that do not have home broadband unable to participate meaningfully in classes and educational activities that have moved on-line to accommodate distance learning. The numbers are staggering: 16.9 million children lack home high-speed internet, including over 30% of Black, Latinx, and Native American households with school-aged children (Alliance for Excellent Education, 2020). Even before the COVID-19 pandemic, Black teens were more likely to face a homework gap due to the digital divide: 25% of Black teens reported that the lack of a home computer or internet service prevented them from completing homework, and 21% relied on public Wi-Fi to complete homework (Andersen & Perrin, 2018). For those households with home broadband access prior to the pandemic, the economic consequences of the COVID-19 pandemic also increase concerns about the ability to pay for household internet service, with 54% of Hispanic users saying they worry about being able to pay for their

home internet services, compared to 36% of Black users and 21% of white users (Vogels et al., 2020).

Federal, State, and Local Broadband Policies and Laws

Unlike other essential infrastructure, broadband is largely provided by private companies, without significant federal oversight over prices or infrastructure development. Nothing in federal law requires internet service providers to provide the same level of service, or to provide service at all, to residents and businesses within their service area, and in 2018 the FCC reclassified broadband as an “informational service” subject to light regulation (rather than a telecommunications service subject to additional federal requirements). This leaves many lower income communities subject to anticompetitive pricing for this essential service, and creates digital deserts in rural areas and areas with higher poverty rates, where private companies may not see an economic benefit from development of this essential infrastructure (Tomer et al., 2020). However, some Tribal and local government entities, where not preempted by state law, are stepping in to fill the voids left by private telecommunications companies, providing public broadband in some 900 communities (Park, 2020).

Federal Broadband Policies and Laws

FCC programs, such as the Rural Digital Opportunity Fund, provide billions of dollars to deploy high-speed broadband to the bidders with the lowest cost request. The U.S. Departments of Agriculture; Housing and Urban Development; and Labor, Employment and Training Administration; and the Institute of Museum and Library Services also administer several programs intended to reduce the digital divide in rural, urban, and tribal areas via loans and grants to fund construction and improvements needed to expand service to underserved communities (Rachfal, 2020).

The FCC also holds authority over several long-standing programs that reduce the economic burdens of broadband services, including E-rate, Lifeline, Connect America, and the Rural Health Care Program. These programs fall under the umbrella of the Universal Service Fund, created in 1934 to ensure access to telephone services, and supported via revenue from telecommunications companies, rather than congressional appropriations (Rachfal, 2020). FCC also recently launched the Connected Care Pilot Program to improve access to telehealth, including funding for the purchase of broadband services for patients that lack home broadband (Holmes, 2020). While these Universal Services programs have provided some relief, the FCC should strengthen and expand these programs to further reduce the digital divide.

There are also federal efforts to collect better information about the digital divide. Concerns over the quality of usage data prompted the 2020 Broadband Deployment Accuracy and Technological Availability Act, which requires the FCC to issue rules governing broadband access data collection and includes measures to increase the accuracy of broadband availability and access maps.

State Broadband Policies and Laws

State governments also have at their disposal a variety of legal and policy interventions to promote broadband, with some states

promoting broad statewide adoption goals, such as Minnesota’s Coordination of Broadband Infrastructure Development law that aims to achieve internet access for all households and business no later than 2022 and requires coordination of broadband installation in conjunction with other infrastructure projects. Conversely, some states hinder efforts by local governments to close the digital divide, using state laws to ban or restrict local governments – such as cities, tribal governments, and utility cooperatives – from providing broadband services (Park, 2020). In *Tennessee v. FCC*, the Sixth Circuit held that federal law did not clearly authorize the FCC to preempt such state laws that place restrictions on municipal broadband services. However, some view community broadband networks as essential to bridging the digital divide (Park, 2020). Eliminating these state law restrictions could increase competition and broadband availability and accessibility in unserved and underserved communities. Federal legislation preventing states from restricting public broadband has been introduced in several legislative sessions, but to date has not been adopted by Congress.

The Legal and Regulatory Response to COVID-19

The U.S. COVID-19 response efforts not only highlight existing inequities in broadband deployment, but also increase the need for reliable broadband at speeds sufficient to support work from home requirements and equitable access to telehealth and remote learning. The equitable provision of reliable broadband is particularly important to prevent a stark expansion of educational disparities, where children that lack home broadband service will fall behind in school.

The Coronavirus Aid, Relief, and Economic Security (CARES) Act includes several programs meant to expand rural broadband deployment and telehealth access, and to assist schools and libraries during closures, including:

- \$13 billion in funding for education agencies to purchase technology, including connectivity, to support remote learning;
- \$3 billion in emergency education relief for states to improve remote learning;
- \$200 million to expand telehealth access; and
- \$50 million to the Institute for Museum and Library Services to “expand digital network access, purchase internet accessible devices, and provide technical support to citizens to address digital inclusion efforts and related technical support.”

While helpful, this funding alone cannot remedy the public health disparities arising from the digital divide.

One of the FCC’s early efforts to eliminate broadband service disruptions was the Keep America Connected pledge, which asked broadband service providers to commit to waiving late fees and not terminating service to small business or residential users that are unable to pay their bills, and to opening their Wi-Fi hotspots to any individual who needs them (FCC News, 2020). These voluntary commitments expired on June 30, 2020, and the FCC’s decision to classify broadband as an “information service” may limit the FCC’s opportunity to require action from broadband providers (FCC News, 2020; Holmes, 2020). The FCC Chairman has urged congressional action to ensure “doctors and patients, students and teachers,

low-income families and veterans, [and] those who have lost their jobs and livelihoods due to the pandemic and the accompanying lockdowns” remain connected throughout the pandemic response (FCC News, 2020). Since mid-March, FCC has also made a variety of short-term adjustments to its affordability programs for the benefit of broadband consumers with increased internet usage needs and uncertain economic futures (Holmes, 2020).

E-Rate Program

Access to high-speed internet has become increasingly essential for school-aged children, particularly as the COVID-19 pandemic has led many schools to opt for continued distance learning into the fall. The FCC’s E-Rate program, codified at 47 C.F.R. § 54.500 et seq., can help ease the burden by providing elementary and secondary schools and libraries with discounts, ranging from 20% to 90%, on broadband services.

As many schools throughout the nation turned to distance learning, the FCC issued a series of orders meant to assist schools and libraries during COVID-19 related closures. First, the FCC waived the gift rules that prevented E-Rate participants from accepting free improved connections or additional equipment for remote learning in a March 2020 order (Holmes, 2020). The waiver allows schools and libraries participating in the E-rate program to accept free upgrades, improved capacity, Wi-Fi hotspots, networking gear, and other equipment and services to support teachers, students, and librarians during the COVID-19 outbreak response. The waiver will allow schools and libraries to partner with service providers to provide mobile hotspots and other wireless devices or direct free broadband services directly to students, and can help “ensure students with limited or no internet connection are connected at home and prevent them from falling behind their peers, furthering the effects of the digital divide.” The FCC order also encourages private sector broadband providers to “partner with schools and libraries to provide mobile hotspots and other broadband-enabled devices to students to help bridge the digital divide during the coronavirus pandemic.”

The FCC also clarified that during COVID-19 related closures, the public can access E-Rate supported Wi-Fi networks while on library and school property (Holmes, 2020). However, the FCC has not taken steps to authorize the use of E-Rate support to provide broadband services more directly to students that lack broadband access at home. Under FCC’s current rules, E-Rate support cannot be used to provide broadband services outside school or library property. Indeed, FCC will reduce E-Rate funding to schools that do provide offsite internet access. Eliminating this funding penalty would encourage more schools to seek other forms of funding to develop offsite broadband directly to student homes (GAO, 2019).

While the FCC has developed a pilot program, the Connected Care Pilot Program, that authorizes the use of Universal Service Funds to support offsite broadband for patients utilizing telehealth services, the FCC has questioned its statutory authority to provide similar offsite E-rate support for offsite broadband for students (GAO, 2019; Holmes, 2020). If the FCC does not move to authorize use of E-rate funds for offsite broadband, federal legislation or directed

funding should be used to clarify the availability of E-rate support for broadband provided offsite to student’s home.

Federal legislation could also help close the homework gap and disparities in access to education during school closures by providing funds for libraries, schools, and tribal entities to purchase hotspots that can be loaned out to provide home internet access or to turn school buses as mobile hotspots (GAO, 2019).

Lifeline Program

The federal Lifeline program, codified at 47 C.F.R. § 54.400 et seq., reimburses telecommunications providers for a \$9.25 monthly discount on broadband and phone services that is passed on to low-income subscribers, with an additional \$25 monthly discount on services provided to rural residents of tribal lands. Eligible households have income less than 135% of poverty guidelines, or participate in federal assistance programs such as Supplemental Nutrition Assistance Program (SNAP), Medicaid, and Head Start, among others. Lifeline subscribers may only utilize the Lifeline discount on one service and must choose to use their discount on either telephone or broadband service, or a bundled service that includes both broadband and phone service. Federal legislation or regulatory revisions that increase the monetary discount provided through Lifeline and allow households to receive a separate discount for telephone and broadband services could help homes that are struggling financially to access broadband services during the COVID-19 pandemic.

To make the program more accessible to a broader array of customers during the COVID-19 pandemic, the FCC recently waived some requirements of the program. Individuals no longer must provide three months of income verification to gain eligibility for the program, making it easier for the recently unemployed to utilize the service (Holmes, 2020). Until August 31, 2020, individuals can confirm their income eligibility for the program using documentation such as a notice of unemployment benefits. In addition, Lifeline providers may not de-enroll subscribers during this waiver period.

The FCC Commissioner has also sought to coordinate with other federal agencies to provide enrollment information to households that are newly eligible for federal services due to the COVID-19 pandemic (Holmes, 2020). Allowing applicants for other federal assistance programs to simultaneously apply for Lifeline support could increase utilization of this program among newly eligible households.

Telehealth and The Rural Health Care Fund

(Note: for additional detailed information on telehealth accessibility and changes to federal and state laws, regulations, and executive orders intended to expand access to telehealth services, see Chapter 16).

The Healthcare Connect Fund, part of FCC’s Rural Health Care Program and codified at 47 C.F.R. § 54.600 et seq., provides significant discounts for broadband connectivity to rural health care providers. As the need for telehealth services has skyrocketed

since the COVID-19 pandemic, FCC has waived the gift rules that previously prevented health care providers participating in the Rural Health Care Program from accepting free improved connections or additional equipment for remote learning.

FCC is also managing \$200 million from the CARES Act to promote telehealth during the COVID-19 response, and an additional \$100 million as part of the newly launched Connected Care Pilot program. Funds from the Connected Care Pilot program will support health care providers' efforts to improve access to telehealth, including offsite broadband services for patients that lack home broadband (Holmes, 2020). This pilot could serve as a model for more permanent programs that bring the benefits of household broadband to many previously disconnected individuals.

Assessment

Many of the programs implemented to provide broadband services during the COVID-19 pandemic provide some relief to individuals that are newly working from home, distance learning, or are newly unemployed. Many households stand to benefit if the FCC were to permanently extend these policy changes. However, the FCC's programmatic responses to the COVID-19 pandemic have failed to bridge the digital divide that prevents many households from accessing the myriad of internet-based school, work, and health related activities that have become routinely internet based as the COVID-19 pandemic persists. Regardless, additional policy changes must be implemented if the United States is to achieve the long-term change needed to quickly, and equitably, close the digital divide and homework gap that preceded the pandemic response, and are heightened by the pandemic response. 🌞

Recommendations for Action

Federal government:

- Congress should enact federal legislation, amending Title 47 of the United States Code, to classify broadband as a telecommunications service, or otherwise provide needed oversight that could help increase competition and eliminate the digital divide.
- Congress should enact federal legislation, amending Title 47 of the United States Code, that prohibits state preemption of local broadband markets and decision-making.
- The FCC should issue an order authorizing the use of E-Rate funding to support offsite broadband access on school buses, at community anchor institutions, and at student homes; and waiving the E-rate funding penalty for schools that provide offsite broadband services. FCC should revise its regulations, at 47 C.F.R. § 54.500 et seq, to codify these changes and expand the E-Rate program.
- The FCC should revise its Lifeline regulations, at 47 C.F.R. § 54.400 et seq., to increase the amount of the Lifeline discount.
- The FCC should work with other federal agencies to bundle Lifeline enrollment with enrollment in other federal programs.
- The FCC should collect data on affordability and availability of broadband service throughout the United States, including demographic data such as language, race, and ethnicity.
- Congress should enact federal legislation requiring broadband infrastructure to be built in conjunction with other government funded construction projects.
- Congress should provide additional funding to libraries, community anchor institutions, and schools for the purchase of mobile hotspots that can be loaned to individuals or used to benefit underserved and unserved communities.

State governments:

- State legislatures should eliminate state laws that preempt communities from establishing municipal broadband services.
- State legislatures and agencies should adopt laws and regulations requiring broadband infrastructure to be built in conjunction with other government construction projects.
- State legislatures should adopt statewide connectivity goals and deadlines.

Local governments:

- Local governments should increase the number of mobile hotspots provided by cities, counties, schools, buses, community anchor institutions, and public health departments. Hotspot-equipped buses can be parked in low-income neighborhoods when not in use.
- City governments should provide free city wide wireless.
- Provide broadband services through community anchor institutions.
- Cities and counties should require broadband infrastructure to be built in conjunction with other government construction projects.
- Local governments should promote competition by creating local public utilities and cooperatives.
- Cities, counties, schools, community anchor institutions, and public health departments should develop public private partnerships to support broadband connectivity.
- Cities and counties should develop community wide connectivity goals.



About the Author

Betsy Lawton, JD, is a senior staff attorney at the Northern Region of the Network for Public Health Law, where she works on a variety of public health law issues, including the health impacts of climate change, mental health and well-being, and rural public health.

References

- Alliance for Excellence in Education (2020). Students of Color Caught in the Homework Gap. Retrieved July 31, 2020, from <https://futureready.org/homework-gap/>
- Andersen, M., & Perrin, A. (2018). Nearly One-In-Five Teens Can't Always Finish Their Homework Because of the Digital Divide. Retrieved July 31, 2020, from <https://www.pewresearch.org/fact-tank/2018/10/26/nearly-one-in-five-teens-cant-always-finish-their-homework-because-of-the-digital-divide/>
- Crock Bauerly, B., McCord, R., Hulower, R., & Pepin, D. (2019). Broadband Access as a Public Health Issue: The Role of Law in Expanding Broadband Access and Connecting Underserved Communities for Better Health Outcomes. *Journal of Law and Medical Ethics*, 47 S2(2019), 39-42.
- Federal Communications Commission (FCC)(2010). Connecting America: The National Broadband Plan. Retrieved July 31, 2020, from <https://transition.fcc.gov/national-broadband-plan/national-broadband-plan.pdf>
- Federal Communications Commission (FCC News)(2020). FCC Chairman Pai Urges Congress to Help Consumers Stay Connected Following End of Keep Americans Connected Pledge on June 30. Retrieved July 31, 2020, from <https://docs.fcc.gov/public/attachments/DOC-365040A1.pdf>
- Holmes, E. N. (2020). Broadband Connectivity and COVID-19: The FCC's Response. Congressional Research Service, LSV10475. Retrieved July 29, 2020, from <https://crsreports.congress.gov/product/pdf/LSB/LSB10475>
- Kruger, L. G., & Gilroy, A. A. (2019). Broadband Internet Access and the Digital Divide: Federal Assistance Program. Congressional Research Service, RL30719. Retrieved July 31, 2020, from <https://crsreports.congress.gov/product/pdf/RL/RL30719/101>
- Park, C. (2002). Community Broadband: The Fast, Affordable Internet Option That's Flying Under the Radar. New America. Retrieved July 31, 2020, from <https://muninetworks.org/sites/www.muninetworks.org/files/Community%20Broadband-%20The%20Fast%2C%20Affordable%20Internet%20Option%20That%27s%20Flying%20Under%20the%20Radar.pdf>
- Rachfal, C. L. (2020). State Broadband Initiatives: Selected State and Local Approaches as Potential Models for Federal Initiatives to Address the Digital Divide. Congressional Research Service, R46307. Retrieved July 31, 2020, from <https://crsreports.congress.gov/product/pdf/R/R46307>
- Tomer, A., Fishbane, L., Siefer, A., & Callahan, C. (2020). Digital Prosperity: How Broadband Can Deliver Health and Equity to All Communities. Retrieved July 31, 2020 from Brookings Metropolitan Policy Program, https://www.brookings.edu/wp-content/uploads/2020/02/20200227_BrookingsMetro_Digital-Prosperity-Report-final.pdf
- Vogels, E. A., Perrin, A., Rainie, L., & Anderson, M. (2020). 53% of Americans Say the Internet Has Been Essential During the COVID-19 Outbreak. Retrieved July 31, 2020 from Pew Research Center, <https://www.pewresearch.org/internet/2020/04/30/53-of-americans-say-the-internet-has-been-essential-during-the-covid-19-outbreak/>
- U.S. Government Accountability Office (GAO)(2019). Report to Congressional Committees: Wireless Internet, FCC Should Assess Making Off-School-Premises Access Eligible for Additional Federal Support. Retrieved July 31, 2020, from <https://www.gao.gov/assets/710/700629.pdf>

COVID-19, Incarceration, and the Criminal Legal System

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SUMMARY. Even before the pandemic, contact with the criminal legal system resulted in health harms on both individual and community levels, with disproportionate impact on people of color. The COVID-19 crisis magnified the deleterious public health impact of policing, prisons, community supervision, and other elements of the United States' vast system of control and punishment. Despite the scientific consensus that prisons and jails needed to be rapidly depopulated to avert disaster, the number of people released has remained small, resulting in explosive outbreaks of COVID-19 behind bars. Depopulation of correctional settings is also rarely paired with meaningful efforts to connect reentering individuals to vital supports. Community supervision systems failed to relax onerous probation/parole requirements, while police have taken on enforcement of physical distancing and other public health orders. Even as COVID-19 is raging, the criminal legal system is resisting changes necessary to facilitate pandemic response. With a focus on incarceration, this Chapter provides an overview of how the U.S. criminal legal system has shaped its COVID-19 response, situating prescriptions in the current debate about divestment from structures of social control in favor of a renewed focus on the social contract. This Chapter will discuss (1) how criminal legal system has exacerbated the current public health emergency and (2) how the United States can use this moment to reform this system and its legal underpinning.

Introduction

On March 28, 2020, Patrick Jones died of COVID-19-related illness. Jones, a 49-year-old African American man, was serving a 27-year sentence for distribution of crack cocaine within 1,000 feet of a junior college. Having spent years behind bars, he had “long-term, pre-existing conditions that are risk factors for developing more severe COVID-19 disease” (DOJ, 2020). Jones was the first person in federal custody to die of COVID-19; tragically, he would not be the last: since his death, over 100 people in federal prisons have met the same fate. As of July 26, 2020, over 600 people have perished in state and local facilities (Dolovich, 2020). Across the nation, more than four out of five of all COVID-19 hotspots are in correctional institutions (N.Y. Times, 2020), resulting in an infection rate that is nearly six times higher behind bars than in the overall population (Saloner et al., 2020).

Long before COVID-19 hit, incarceration (and the larger criminal legal system) was already understood as a source of multiple health harms. The United States' correctional institutions are characterized by widespread overcrowding, lack of basic sanitation, substandard health care, and many other issues symptomatic of abuse and neglect of people behind bars. The dismal health status of its enormous correctional population and the failure to provide adequate reentry supports explain the link

between the United States' status as the world's leading jailer and its position at the bottom of public health rankings among peer nations. In addition to the racial justice, fiscal stewardship, and other reform imperatives, public health data demonstrating individual and community detriment from incarceration helped amplify calls for reform. Aside from marginal sentencing reform, these calls went largely unheeded.

COVID-19 found in the criminal legal system precisely the kind of dysfunction that most efficiently fuels its spread. After discussing how the structure and function of the correctional system made it highly vulnerable to the pandemic, this Chapter focuses on the role of the correctional system in shaping COVID-19 spread. Acknowledging that incarceration is but one piece of a much larger carceral ecosystem, we conclude with a discussion of broader structural criminal legal reforms vital to bringing COVID-19 under control.

The Criminal Legal System as a Public Health Crisis Before COVID-19

With 5% of the global population, the United States is home to 20% of those incarcerated (Franco-Paredes et al., 2020). People of color are overrepresented: in 2015, the incarcerated population was 56% Black and Latinx. Disturbingly high rates of incarceration, coupled with harsher sentencing and other factors that decrease chances

of success post-release, result in a bloated criminal legal system filled with people whose demographics do not reflect the general population. Carceral institutions are also woefully overcrowded due to overcriminalization and disinvestment in health and social supports. At least 400,000 persons with some type of mental illness are incarcerated – about 18% of the incarcerated population. Poverty and race play a significant role in incarceration rates, with “40[%] of crimes attributed to poverty and 80[%] of incarcerated persons self-identified as low-income” (FPWA, 2019).

Contact with the criminal legal system is a public health crisis that affects millions of Americans and their families. Poor people, living in communities targeted for heightened enforcement, too often find themselves caught in a spiral of citations, arrests, fines, and court fees that drive them deeper into poverty and create barriers to employment, education, and public benefits. While engaged in this system on either side of correctional institutions, people are barred from full participation as members of their community, by both law and institutional practice. Those who go to jail or prison experience poor diets, unsanitary and dangerous physical conditions, violence, stress, and separation from family. On release, individuals experience enormous barriers to reentry, which often leads to significant health detriment, including by shaping social determinants of health like housing, health services, and financial support. As an extreme example, those reentering from carceral institutions are 130 times more likely to die of a drug overdose than the general public (Johnson & Beletsky, 2020).

The Criminal Legal System in the Context of COVID-19

Despite marginal pre-pandemic change, existing legal and policy tools have failed to substantially reform America’s correctional institutions and the broader system that feeds – and is fed – by them. In the context of a pandemic, the dysfunction of this system has been thrown in sharp relief. When COVID-19 hit, there were wide calls for depopulation and decarceration of correctional institutions, reflecting concerns about previous infectious disease outbreaks behind bars (Franco-Paredes et al., 2020). Such calls drew on existing, but rarely deployed, legal authority to depopulate carceral institutions held by wardens, governors, and other actors in the criminal legal system to address situations exactly like these. As discussed below, there have been myriad efforts to reduce the incarcerated population using various legal and policy tools, both from within (e.g., executive orders) and challenging the system (e.g., litigation).

Federal Actions to Reduce Prison Populations

In the context of the pandemic, the Bureau of Prisons announced a number of efforts to address COVID-19 risk, including reducing federal correctional populations (BOP, 2020). While thousands were released, observers decried the lack of transparency, substantial delays in implementation, and failures of the risk-and-needs assessment tool developed by the Department of Justice to “classify prisoners and determine who may be eligible for rehabilitative programs, or even early release” (Goldsmith, 2020). Additionally, individual releases are frequently opposed by federal prosecutors. Thus, despite federal assurances of efforts to decrease the incarcerated population, steps taken to date are largely symbolic.

State Actions to Reduce Prison Populations

Several states also took steps to reduce the prison population, most often by releasing those with low-level or non-violent offenses and the medically vulnerable. Some examples drawn from tracking by the Prison Policy Initiative (2020):

- California reduced bail for misdemeanors and some low-level felony offenses, which has shrunk the prison population by up to 45%; “early releases of people held for ‘low-level’ offenses have reportedly helped drop the jail population by half” in Washington County, OR. The local jail population in Philadelphia “has dropped by 17% since the beginning of April, following special court hearings to release hundreds of people held for low-level charges, cash-bail, and ‘nonviolent’ charges.”
- Ohio courts “began to issue court orders and conduct special hearings to increase the number of people released from local jails... reducing [one county jail’s] population by more than 30%.” Miami-Dade County jails in Florida and the Northwestern Regional Adult Detention Center in Virginia have both decreased the average daily population by about 20%.
- An April order from the Massachusetts Supreme Judicial Court (SJC) “authorized the release of people held in jails pretrial for ‘nonviolent’ offenses and those held on technical probation and parole violations,” resulting in a 20% decrease in the prison population in Plymouth and Norfolk counties and an 11% decrease in the population at the Bristol County jail.

Many states and municipalities took similar steps to reduce incarcerated populations, but much of the action is too little, and too late. While almost 80,000 people incarcerated are confirmed to have contracted COVID-19 as of July 25, one project found an overall population reduction of over 60,000 from jails and over 30,000 from prisons (Dolovich, 2020). As a result, people behind bars and correctional staff will be infected and die. The existence of COVID-19 hotspots inside carceral institutions will also substantially affect the overall shape of the pandemic in surrounding communities.

Legal and Policy Actions Taken

From a public health perspective, it is clear that we must reduce the number of people incarcerated. Unfortunately, efforts to secure release have been largely unsuccessful (Dolovich, 2020). Courts have turned back claims under the Eighth Amendment’s ban of “cruel and unusual punishment,” as well as under state laws. Agencies and courts have made only limited use of compassionate relief mechanisms for people at higher risk (due to both the aging incarcerated population and the inadequacy of health care in carceral institutions) (Dolovich, 2020). Governors have largely opposed depopulation efforts, despite ample legal authority to deploy them (Becker, 2020).

Instead of depopulation, correctional officials in many jurisdictions took measures that satisfy political and judicial pressure by signaling their ability to meet the challenges posed by COVID-19 behind bars. This has included providing somewhat better access to soap and other sanitation products, distributing personal protective equipment (PPE), widespread lockdowns to enforce

social distancing, and introducing privileges of unclear infection control utility, such as access to movies and additional dessert options.

COVID-19 Exacerbates Issues in the Criminal Legal System

It is both a moral and public health imperative to maximize the number released, but also to minimize the number of those entering the criminal legal system. Experts understand that carceral institutions, halfway houses, and other involuntary congregate settings are hotspots for disease transmission. Moreover, “[o]vercrowding, insufficient sanitation, poor ventilation, and inadequate healthcare in prisons contribute to enabling these institutions as breeding grounds of infectious disease outbreaks. Detention and incarceration of any kind involves large groups of people living in cohorts in confined spaces creating many challenges for curbing the spread of COVID-19” (Franco-Paredes et al., 2020).

How COVID-19 Exacerbates Existing Reentry Issues

Effective public health is predicated on the social contract – an informal agreement to make some individual sacrifices for the benefit of the community. Departure from shared values, equity, and investments in human capital have ushered in a fraying of this contract, resulting in growing income inequality and structural oppression. Overall, U.S. cities invest more in criminal legal systems than in agencies responsible for health and social support, combined (Health in Justice Action Lab, 2020). The health sequelae of these investment priorities had become visible even before the current pandemic, most vividly in the declining life expectancy in the United States.

The global pandemic makes the need to depopulate jails and prisons all the more urgent, but efforts to do so must always be coupled with increased supports for people through the reentry process. Indeed, without these supports, already vulnerable populations leaving jails and prisons are at increased risk for health problems, mental health distress, poverty, relapse, and homelessness (Johnson & Beletsky,

Table 31.1: Barriers to Reentry and COVID-19

BARRIER	WHY THIS POSES A BARRIER & COVID-19-SPECIFIC CONSIDERATIONS
Transportation	Many individuals do not have anyone to pick them up from jail or prison. COVID-19 exacerbates this barrier as public transportation may be more limited. The person picking them up might also be concerned about potential exposure. Challenges continue as individuals must find transportation to services, jobs, or other mandated locations.
Clothing, Food, & Amenities	Most individuals are released with whatever they wore upon entering or receive a single change of clothing that may not fit. They often receive no information about food resources. Any information received might be outdated or inaccurate as many community services – and clothing stores – are temporarily or permanently closed.
Financial Resources	Most individuals do not receive any money for food, transportation, or shelter. In pre-COVID-19 times, this could lead to homelessness and reliance on inadequate public assistance systems (e.g., food pantries or shelters). COVID-19 presents even greater challenges to access. State or local agencies that administer public assistance may be closed to the public, while community organizations that provide public assistance are grappling with increased demand and maintaining infection prevention measures.
Documentation	Individuals may not have a valid state-issued identification card and, if they do, that card may have expired during their incarceration. COVID-19 closures might mean waiting even longer for state and local agencies to reopen before obtaining IDs.
Housing	Because “[r]eentry often relies heavily on person-to-person contact as well as group settings and living situations,” traditional reentry supports like halfway houses are not feasible. People reentering “need stable and appropriate lodging to observe CDC guidelines for hygiene and social distancing” (Johnson & Beletsky, 2020).
Employment & Education	“[T]hose reentering are typically barred from receiving cash assistance or unemployment, which means they rely on jobs to survive.” Both the stigma of a record and unemployment could push individuals into jobs with “extreme levels of risk, including in the illicit economy,” threatening not only their safety, but their freedom (Johnson & Beletsky, 2020).
Health Care	As states and localities release hundreds of people, they must also take steps to ensure treatment continuation. “An estimated 65% of the 2.3 million people [incarcerated] have a diagnosable [SUD], more than seven times the background rate” and “[n]early 15% of incarcerated men and 30% of women also have diagnosable mental health disorders” (Beletsky, 2019). “On top of existing barriers, people reentering society will be less able to reach medical providers or clinics because of social distancing” (Johnson & Beletsky, 2020).
Support Systems	Many without community connections have no organic support and limited knowledge of available resources. COVID-19 exacerbates these challenges because “those just reentering society, unable to even go to a public library to use a computer, lack the credit for a cell phone plan nor the means to get one since stores are closed” (Johnson & Beletsky, 2020).

Table 31.2: The Sequential Intercept Model as applied to COVID-19

INTERCEPT	PROPOSED ACTION	COVID-19-SPECIFIC CONSIDERATIONS
0 – Community Services	Stop relying on police officers as de facto first responders. Utilize mobile crisis outreach teams if someone is experiencing behavioral health crises, interpersonal violence, or other situations. Divert people to crisis services (rather than jails or emergency departments).	Reducing initial interactions with the criminal legal system (e.g., reducing “stop and frisk” that places individuals in close contact with often unmasked officers) addresses the particular health harms COVID-19 presents.
1 – Law Enforcement	This intercept is characterized by both better training (i.e., educating police on how to interact with individuals based on their needs) and person/situation-specific training (i.e., for dispatchers to ensure that the appropriate individual(s) responds to a crisis).	Educate first responders on operating in the context of COVID-19. As protests continue, train law enforcement to employ de-escalation techniques that limit health harms (e.g., stop using tear gas that causes people to cough and spread COVID-19).
2 – Initial Detention & Initial Court Hearings	Focus on diverting individuals from this intercept entirely. Courts should order pretrial supervision and diversion to reduce any episodes of incarceration.	Courts must resist the urge to incarcerate people during the pandemic. If detained, screen individuals for health conditions, including COVID-19, and other needs.
3 – Jails & Courts	Once a person is in “the system,” interventions should focus on providing supportive services to protect individuals from further harm by their interactions with criminal legal systems.	Employ measures directed both at staff (e.g., practicing infection control by masking) as well as individuals (e.g., provide PPE). Conduct frequent COVID-19 screening.
4 – Reentry	Reentry planning is essential to breaking the cycle of interaction. This includes discharge planning similar to hospitals and “warm hand-offs” (transporting person directly to services that increase positive outcomes).	During the pandemic, reentry must not only be managed remotely, but also unequivocally include housing, transportation, and financial assistance.
5 – Community Corrections	This intercept is often where the “cycle” begins as individuals violate parole or probation – often unintentionally or out of desperation – and are returned to incarceration.	Interventions must include specialized, potentially remote, community supervision (i.e., for people with SUD); continued treatment of physical (including COVID-19) and mental health conditions; and expanded access to services.

2020). Serious mental illness, addiction, poverty, and other social determinants of health – not to mention an ongoing pandemic – exacerbate and cause additional challenges. The Urban Institute’s Justice Policy Center identified eight factors that prevent successful reentry, offering solutions to such barriers (La Vigne et al., 2008). Table 31.1 summarizes these factors in the context of COVID-19.

Reducing Interactions with the Criminal Legal System Post-COVID-19

Interactions with the criminal legal system (most commonly in the form of policing) already result in health harms, particularly dangerous for people of color, who disproportionately experience more lethal police action than their white counterparts. To address COVID-19, such interactions must be limited not only to accommodate social distancing requirements, but also because police brutality and murders of unarmed people represent a separate, ongoing pandemic (Stolberg, 2020). Each point of

contact with the criminal legal system – “from the point of crisis pre-arrest, through detention, and post-release” – is an opportunity to reduce the health harms of these systems (Beletsky, 2019). One conceptual framework for harm reduction is the Sequential Intercept Model, which can be used to conceptualize opportunities to better serve people experiencing physical, behavioral, and mental health challenges within the criminal legal system. Although more upstream measures that reduce initial entry to the criminal legal system are needed, the Model (discussed in the context of COVID-19 in Table 31.2) provides an important guiding framework for the opportunities to “off-ramp” individuals out of the criminal legal system. 🌞

Recommendations for Action

Federal government:

- The federal Bureau of Prisons should:
 - o Continue decarceration efforts while ensuring reentry services are expanded accordingly;
 - o Restore the Obama-era program that gave cell phones to those who cannot afford a phone line (1) for communication with family, employers, and social services and (2) as a way to check in with parole/probation, register for benefits, contact social workers, and schedule appointments with health care providers;
 - o Ensure access to shelter upon release, including providing temporary housing (e.g., hotel rooms) to individuals who need assistance or a safe space to quarantine post-release;
 - o Conduct frequent (daily or weekly) COVID-19 screenings on all staff and individuals incarcerated in federal facilities.
- The Department of Health and Human Services should continue to encourage states to use emergency 1135 waivers, which allow states to use Medicaid funds for housing and moving expenses.
- Congress should eliminate the “inmate exclusion” in Medicare and Medicaid, opening the door for the use of federal health dollars in correctional settings.
- Legislators should change laws, including controlled substances and other statutes criminalizing health and economic vulnerability, to shrink the footprint of the criminal legal system.

State governments:

- State correctional officials should:
 - o Expand COVID-19 testing of individuals and correctional officers in carceral institutions;
 - o Ensure transportation upon release;
- o Provide financial assistance upon release;
- o Provide temporary ID cards to those without a valid ID upon release.
- Legislators and appropriate agencies should:
 - o Change statutes, regulations, and institutional policies to ensure individuals are not barred from seeking public assistance for housing due to their record;
 - o Change statutes, regulations, and institutional policies to relax conditions of probation and parole that mandate obtaining employment, substance use treatment, housing, or continuing education.
- Legislators should mandate and fund:
 - o Virtual job counseling and access to online classes for those reentering (and technology resources for those who can no longer access places with publicly available resources);
 - o The provision of expanded reentry services and virtual capacity to ensure the continuation of such services;
 - o Services to reduce COVID-19 spread post-incarceration, including:
 - Access to shelter upon release, including providing temporary housing (e.g., hotels) to individuals who need assistance or a safe space to quarantine;
 - Provision of medications during and after incarceration;
 - Testing for COVID-19 upon release, and again two weeks after;
 - Provision of naloxone (opioid overdose reversal drug) to individuals with SUD;
 - Assistance with re-enrolling in Medicaid to those who qualify.

licensing for people otherwise qualified and not a risk.

Local governments:

- City and county jail officials should:
 - o Expand COVID-19 testing of individuals and correctional officers in carceral institutions;
 - o Ensure transportation upon release;
 - o Provide financial assistance upon release.
- Local governments should mandate and fund:
 - o Virtual job counseling and access to online classes for those reentering (and technology resources for those who can no longer access places with publicly available resources);
 - o Expanded reentry services and virtual capacity to ensure the continuation of such services:
 - Services to reduce COVID-19 spread and other health harms post-release, including:
 - Access to shelter upon release, including providing temporary housing (e.g., hotels) to individuals who need assistance or a safe space to quarantine;
 - Provision of medications during and after incarceration;
 - Testing for COVID-19 upon release, and again two weeks after;
 - Provision of naloxone (opioid overdose reversal drug) to individuals with SUD;
 - Assistance with re-enrolling in Medicaid to those who qualify.
- Legislators should enact “ban the box” ordinances prohibiting the check box that asks if applicants have a criminal record in hiring applications.

About the Authors

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Leo Beletsky, JD, MPH, holds an interdisciplinary appointment with the School of Law and Bouvé College of Health Sciences at Northeastern University. His expertise is in the public health impact of laws and their enforcement, with special focus on infectious disease, substance use and addiction, occupational safety of first responders, and policing as a structural determinant of health. He directs the School of Law's Health in Justice Action Lab.

References

- Becker, D. (2020). Mass. High Court Urges Governor to Use His Powers to Release Prisoners Because of COVID-19. *WBUR*. Retrieved July 26, 2020, from <https://www.wbur.org/news/2020/04/28/sjc-charlie-baker-executive-powers-furloughs-parole-covid-19-coronavirus>
- Beletsky, L. (2019). Memorandum: Treating Substance Use and Mental Health Disorders in Correctional Settings. Retrieved July 5, 2020, from https://d5e387bc-53d6-4733-81d9-1157ea24c80e.filesusr.com/ugd/1367d9_f328af27fec44a619ec0d04ce2e56afa.pdf
- Dolovich, S. (2020). UCLA Law Covid-19 Behind Bars Data Project. Retrieved July 5, 2020, from <https://law.ucla.edu/academics/centers/criminal-justice-program/ucla-covid-19-behind-bars-data-project>
- Federal Bureau of Prisons (BOP)(2020). BOP Implementing Modified Operations. Retrieved July 26, 2020, from https://www.bop.gov/coronavirus/covid19_status.jsp
- Federation of Protestant Welfare Agencies, Inc. (FPWA)(2019). Ending the Poverty to Prison Pipeline. Retrieved July 5, 2020, from <https://www.fpwa.org/wp-content/uploads/2019/04/FPWAs-Ending-the-Poverty-to-Prison-Pipeline-Report-2019-FINAL.pdf>
- Franco-Paredes, C., Jankousky, K., Schultz, J., Bernfeld, J., Cullen, K., Quan, N. G., Kon, S., Hotez, P., Henao-Martinez, A. F., & Krsak, M. (2020). COVID-19 in Jails and Prisons: A Neglected Infection in a Marginalized Population. *PLoS Neglected Tropical Diseases*, 14(6), e0008409.
- Goldsmith, K. (2020). The Status of the First Step Act One Year Later. *American Bar Association Journal*. Retrieved July 5, 2020, from <https://www.abajournal.com/magazine/article/the-status-of-criminal-justice-reform-one-year-later>
- Health in Justice Action Lab (2020). Carceral Resource Index. Retrieved July 9, 2020, from <https://www.healthinjustice.org/carceral-resource-index>
- Johnson, S., & Beletsky, L. (2020). Helping People Transition from Incarceration to Society During a Pandemic. Retrieved July 5, 2020, from <https://ssrn.com/abstract=3608298>
- La Vigne, N., Davies, E., Palmer, T., & Halberstadt, R. (2008). Release Planning for Successful Reentry: A Guide for Corrections, Service Providers, and Community Groups. Retrieved July 5, 2020, from <https://www.urban.org/sites/default/files/publication/32056/411767-Release-Planning-for-Successful-Reentry.PDF>
- New York Times (N.Y. Times)(2020). Coronavirus in the U.S.: Latest Map and Case Count. Retrieved July 9, 2020, from <https://www.nytimes.com/interactive/2020/us/coronavirus-us-cases.html#click=https://t.co/ay2Xtf0m5G>
- Prison Policy (2020). Responses to the COVID-19 Pandemic. Retrieved July 5, 2020, from <https://www.prisonpolicy.org/virus/virusresponse.html>
- Saloner, B., Parish, K., Ward, J. A., DiLaura, G., & Dolovich, S. (2020). Research Letter: COVID-19 Cases and Deaths in Federal and State Prisons. *JAMA*.
- Stolberg, S. G. (2020). 'Pandemic Within a Pandemic': Coronavirus and Police Brutality Roil Black Communities. *New York Times*. Retrieved July 20, 2020, from <https://www.nytimes.com/2020/06/07/us/politics/blacks-coronavirus-police-brutality.html>
- U.S. Department of Justice – Federal Bureau of Prisons (DOJ)(2020). Press Release: Inmate Death at FCI Oakdale I. Retrieved July 26, 2020, from https://www.bop.gov/resources/news/pdfs/20200328_press_release_oak_death.pdf

Supporting LGBT Communities in the COVID Pandemic

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SUMMARY. LGBT individuals suffer disproportionately in the COVID-19 pandemic. They are likely to be exposed to COVID-19 in greater numbers and suffer to a greater degree if they contract the disease. They are more likely to lose access to essential medical services, including gender confirmation and HIV medications. They are likely to suffer economic harms to a greater degree, since they are more likely to work in industries with exposure to, and likely to close because of COVID-19. They also are more likely to experience mental and emotional harms arising from the isolation, or sheltering-in-place COVID-19 necessitates. Such isolation often occurs with hostile or violent family members, while LGBT safe-spaces, organizations, institutions, and events, such as LGBT pride and LGBT centers are shut down or go virtual. This can take a toll on physical, emotional, and mental health, especially for youth and elderly LGBT individuals. Finally, when LGBT individuals seek assistance from elsewhere, including through social services, homeless shelters, and welfare, they often suffer discrimination. All these harms fall even more disproportionately on LGBT people of color and transgender individuals. To combat these harms, policymakers must implement stringent antidiscrimination protections and policies that cover the needs of LGBT individuals such as access to certain medical services. But more importantly, they should ensure that the LGBT organizations providing these services in a safe space remain funded and open. They should also collect data on the LGBT community.

Introduction

As Michelle Bachelet, the UN High Commissioner for Human Rights, has acknowledged, “LGBTI people are among the most vulnerable and marginalized in many societies, and among those most at risk from COVID-19.” The pandemic has widened existing inequity in society and the LGBT community is no exception.

The harms that LGBT individuals will experience as a result of the COVID-19 pandemic fall into several categories: (1) First, there are COVID-related health harms. There is reason to believe that LGBT individuals face higher morbidity and mortality risk from the pandemic. (2) Other medical harms including lack of access to necessary medical services such as gender confirmation or HIV treatment during the pandemic. (3) Mental and emotional health harms arising from the isolation, or sheltering-in-place COVID-19 necessitates. Such isolation often occurs with hostile or violent family members. This can take a toll on physical, emotional, and mental health, especially for youth and elderly LGBT individuals. (4) Economic insecurity, given that LGBT individuals are more likely to work in industries with exposure to, and likely to close because of COVID-19. (5) Discrimination in employment and access to social services. Finally, (6) lack of community support as LGBT community organizations founder and close.

Each of these harms reinforce each other. Health harms can cause job loss and economic insecurity, and vice versa. Mental health and

addiction burdens can take a toll on physical health, and render LGBT individuals ineligible for social services and welfare, which worsens these harms.

Next, this Chapter considers the increased harms that LGBT minorities—people of color and transgender individuals, face along all these axes. It concludes by considering solutions, and explaining why an inclusive approach to the LGBT experience can be a valuable tool in the broader fight against COVID-19.

COVID Related Health Issues

Experts have suggested that LGBT individuals might face higher risks if they contract COVID-19. As numerous LGBT organizations explained in an open letter, LGBT individuals have underlying health problems at higher rates than the general population that can magnify the risk of COVID-19. For example, they use tobacco, and also have asthma, at rates 50% higher than the general population, which might increase their vulnerability to respiratory conditions such as COVID-19. The community also has much higher rates of HIV and cancer, which can leave some LGBT individuals immunocompromised and vulnerable to COVID-19. While research is limited, people living with HIV are more likely to have cardiovascular and chronic lung diseases that increase their vulnerability. These concerns are compounded for minority groups—for example, half of all black cisgender men who have sex with men (MSMs) and half of transgender women will be

diagnosed with HIV in their lifetime. Finally, as discussed later in this Chapter, LGBT individuals are more likely to face economic insecurity and homelessness, which increases their exposure and vulnerability to COVID-19.

If they contract COVID-19, LGBT individuals are more likely to face barriers to receiving health care. Discrimination in health care settings remains high, and numerous LGBT individuals report avoiding health care settings except in emergency situations. Further, rates of insurance coverage are lower: 17% of LGBTQ adults do not have any kind of health insurance coverage, compared to 12% of non-LGBTQ adults (Whittington et al., 2020). Indeed, transgender individuals who face barriers to accessing bathrooms that match their gender in workplaces and elsewhere might even be unable to wash their hands to reduce COVID-19 risk (Hensley-Clancy, 2020).

LGBT individuals may also experience medical events at higher rates than the rest of the population. Transgender individuals may need access to gender confirming medication. People living with HIV need access to lifesaving drugs that they must take on a daily basis. COVID-19 has limited access to these services. For example, the Johns Hopkins Center for Transgender Health has postponed gender-affirming surgeries, and “has a moratorium on new patient intakes due to the retasking of personnel and resources to the COVID-19 response.” Similarly, as I learned in an interview with the Chief of Staff of the Los Angeles LGBT Center, one of the nation’s largest providers of LGBT health services in the nation, their clients feared loss of access to medication and other services. Crowding as individuals try to access these resources can increase risk for COVID-19.

LGBT individuals have among the highest rates of suicidality and substance abuse, with 40% of transgender individuals attempting suicide at some point in their lives, and LGBT youth attempting suicide at three times the rate of heterosexual youth. Similarly, LGBT adolescents are nearly twice as likely as their non-LGBT peers to have used some kind of illicit substance. Isolation and lack of supportive surroundings are linked to suicidality and relapses, or increased substance abuse (The Fenway Institute, 2020).

Such issues are particularly pronounced among certain subpopulations. First, LGBT youth often lack access to supportive surroundings. Research suggests that only a third of LGBT youth have accepting parents, and an additional third experience outright rejection, which increases suicide risk and depression exponentially (The Trevor Project, 2020). With shelter-in-place orders, CBS News reports, LGBT youth find themselves isolated at home—or what one interviewee called a “war zone.” Some experience death threats. Unsurprisingly, NPR reports that the Trevor Project, a suicide prevention organization for LGBTQ youth, has seen in some cases twice the level of outreach to the organization during the pandemic than earlier in 2020.

Particularly problematic is the inability of students to access supportive resources outside the home. Schools provide material resources: 30% of youth in foster care, and 40% of homeless youth identify as LGBT. School closures mean limited access to food and other resources (Whittington et al., 2020). Although less than half

of schools nationwide have organizations dedicated to supporting LGBT youth, school closures might also mean that students are unable to access those resources. University closures can present even more urgent situations, with some students forced to return to homes with which they may have cut ties, or to families that continue to misgender them—for example, referring to male transgender children as female. One student tells a reporter how “her parents call her by the wrong name, use the wrong pronouns.” Apart from being cut off from support, LGBT youth may not be able to safely access transition or HIV related medication when living with their parents (Hensley-Clancy, 2020).

Older LGBT individuals face similar issues. Even before COVID-19 struck, LGBT individuals 50 years of age and older were twice as likely to live alone than their straight counterparts, half as likely to have significant others or close relatives, and four times less likely to have children; almost one quarter had no one to call in the case of an emergency (SAGE USA, 2020). Further, this population is more likely to experience health concerns, including diabetes, asthma, heart disease, HIV, cancer, hypertension, and disabilities (SAGE USA, 2020). LGBT older people are far more likely to rely on “chosen” family—close friend groups—for help. But since they do not live with these individuals, and close friends are likely to age at the same rate, such reliance can be of limited help during COVID-19’s spread. And, laws such as the Family Medical Leave Act do not allow elders’ chosen family to take time off to care for them if they were to become sick (SAGE USA, 2020).

Finally, even among the rest of the LGBT community, the isolation that COVID-19 necessitates can lead to harms. While 35% of straight women experience rape, physical violence, or stalking by an intimate partner, the number rises to 44% of lesbians and 61% of bisexual women. Similarly, 54% of transgender and non-binary respondents experience intimate partner violence in their lifetimes. Further, as the next Section describes, because of higher rates of poverty and stigma, and limited access to health insurance, many LGBT individuals—whether youth, elderly, or others, are unable to leave toxic home environments (Human Rights Campaign Foundation, 2020a). The isolation that COVID-19 requires thereby exacerbates severe harms that LGBT individuals experience at home.

Economic Issues

Health harms can reinforce the economic harms that LGBT individuals face. As the premier research organization on LGBT issues, the Williams Institute, and a lead advocacy non-profit for LGBT equality, the Human Rights Campaign, have emphasized, “LGBTQ Americans are more likely than the general population to live in poverty and lack access to adequate medical care, paid medical leave, and basic necessities during the pandemic” (Whittington et al., 2020). The poverty rate among LGBT individuals is 22%, compared to 16% among non-LGBT individuals. Further, one in five LGBTQ adults have not seen a doctor when needed for financial reasons.

Against this background, COVID-19 has struck the community hard. LGBT individuals are overrepresented in industries that result in high exposure to the coronavirus. Further, many of these industries are most likely to be shut down as a result of the

pandemic, increasing unemployment in the community. Research shows that the top five industries in which LGBT individuals work—comprising 40% of LGBT employment—are hospitals, restaurants and food services, K-12 education, colleges and universities, and retail (Whittington et al., 2020). By contrast, only 22% of non-LGBT individuals work in these industries. Even with short term economic stimulus, the stress on these industries means that LGBT individuals may face long-term unemployment.

Discrimination

LGBT individuals face discrimination in the workplace. In 2018, the Human Rights Campaign found that nearly half of all LGBT workers remain closeted at work. And, only about half of straight/cisgender employees reported they would be “very comfortable” with an LGBT coworker. A recent Supreme Court ruling has held that LGBT employees are protected from discrimination under federal law. But employment discrimination protections are hard to apply if the employer is not open about the reasons for the negative employment action. Further, commenters believe that the Court will hold that at least some employers can discriminate against LGBT individuals for religious reasons. Loss of employment can increase the economic and medical harms that LGBT individuals face.

COVID-19 work-from-home practices have had a mixed effect on LGBT individuals, particularly transgender individuals. Some transgender individuals report relief because teleworking allows them to use their bathroom at home, rather than worry about whether they can use their bathroom of choice at work. But others complain that Zoom is connected to their emails, and therefore uses their “deadnames,” that is, names assigned to them at birth that misgender them. Further, doing business by phone rather than in person also means that some transgender individuals are misgendered as their conversation partner must rely on their voice rather than their appearance (Hensley-Clancy, 2020).

Because of the high degree of economic harms and homelessness LGBT individuals face because of familial rejection and violence, they also rely on government services such as shelters and welfare programs. LGBTQ shelters have reported a significant increases in intake—one D.C. shelter reported a tripling of intake in the first month of the pandemic. But as shelters have to engage in social distancing, many have reduced capacity, leaving LGBT individuals homeless, or only able to go to shelters that engage in discriminatory practices (Velasco & Langness, 2020).

Further, numerous Trump administration agencies have rescinded rules that prevent anti-LGBT discrimination across a range of programs, including shelters, access to healthcare, access to services funded by federal healthcare grants, and the like (Velasco & Langness, 2020). Faith-based service providers, including medical service providers, have claimed religious exemptions to discriminate against same-sex couples. This has involved situations where medical institutions have refused to provide information to same-sex spouses (Goldberg & Wechsler, 2020). Such religious entities might also engage in COVID-19 related care. For example, a field-hospital in New York requested “Christian volunteers,” who would adhere to its Statement of Faith, which

explicitly rejected transgender individuals and marriage equality, as NBC reports.

Loss of Community Support

LGBT individuals are facing a loss of community support due to COVID-19. The year has seen the endangering of prominent LGBT institutions: the oldest running gay bar in San Francisco has shut down, the country’s third oldest LGBT newspaper is close to closing its doors, and indeed, LGBT pride celebrations around the country were cancelled or held online.

These consequences might seem trivial to outside observers, but are of vital importance to the LGBT community. As one commentator eloquently put it in the Atlantic, “queer gatherings are a rejection of queer isolation: of hiding in the closet, of believing oneself to be alone in one’s identity, of fearing that embracing one’s truth would result in physical harm” (Kornhaber, 2020). Unlike other communities, LGBT individuals must seek out LGBT gathering spaces, such as bars and community support groups, rather than rely on families. Sometimes, this has resulted in LGBT individuals taking risks that have led to contracting COVID-19 and death (Kornhaber, 2020).

With the cancelling of pride celebrations in particular, members of the LGBT community have expressed loneliness. Further, pride celebrations are often key for LGBT organizations to survive. The Center on Colfax—Denver’s LGBT Center—forfeited around \$1 million from being unable to produce PrideFest—which it would have used to support mental health and legal services. Cummings from the Los Angeles Center, which also provides medical care, housing, and other services, explained that funding sources have dried up, as organizations do not realize the COVID-19 related support these organizations provide. This will further endanger the support that it can provide for the community.

Harms to Subpopulations

The harms arising from COVID-19 fall disproportionately on LGBT individuals of color and transgender individuals as the figure below lays out. While the figure focuses on economic disparities arising from COVID-19, these disparities appear in other areas. For example, while 12% and 17% of the general population and the LGBT community respectively lack health insurance, those figures jump higher to 22% for transgender individuals, and 32% for transgender individuals of color. This increases their exposure to COVID-19 and secondary harms as laid out above.

Solutions

Solutions should be adopted at three levels. First, the Trump administration’s decisions to repeal antidiscrimination protections for the LGBT community should be reversed. Indeed, the Supreme Court recently held that discrimination based on transgender status (that is, not conforming to the sex one is assigned by birth) and on sexual orientation (that is, discriminating based on the sex to which an individual is attracted) were both forms of prohibited sex discrimination. While the Court limited its holding to the employment context, its reasoning extends more broadly. For example, the Affordable Care and Fair Housing Acts prohibit sex discrimination in medical contexts and shelters respectively.

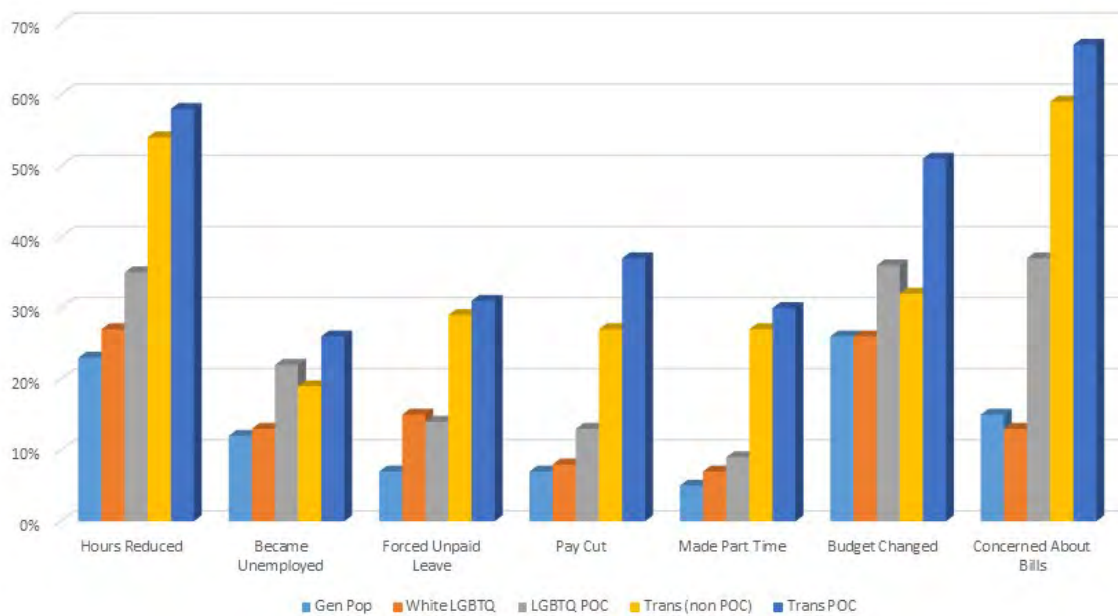


Figure 32.1: Effects of COVID-19 on LGBT Subpopulations. Source Human Rights Campaign Foundation (2020b and 2020c).

Agencies must recognize this legal change promptly, and Congress should exercise its oversight power to make sure that they do so.

Secondly, states and federal entities should provide assistance targeted towards LGBT individuals and organizations that are foundering at this time. Assisting LGBT organizations is vital for a group of individuals who may lack familial support. Importantly, LGBT organizations may lack access to paycheck protection program funding, and do not get access to funding directed to organizations providing COVID-19 support. But LGBT individuals are most likely to get supportive and non-discriminatory care at these LGBT organizations, and thus are likely to go to these organizations for relief. These organizations have historically provided gathering places for LGBT youth and elders; they should be well-resourced as they shift to changing the way in which they provide services. Rather than try to reinvent the wheel, policymakers should deputize these organizations for providing community services.

Targeted assistance should also involve data collection on LGBT individuals at times of COVID-19 testing, and in providing other services, so that we can better understand community needs. So far, Pennsylvania is the only state to require such testing. Similar legislation is expected to pass in California. Other states and the federal government should take similar steps. (Lang, 2020).

Further, the government should provide advice and services with an eye to LGBT individuals. For example, state and local governments should ensure that HIV testing and gender confirmation treatment remain available even during times of shelter-at-home. Further, they should not require identification for accessing services, as transgender individuals might have identification that misgenders them, and does not conform to their appearance, which may result in a denial of services.

Third, given the economically precarious state of LGBT individuals, measures that would provide assistance to vulnerable communities

in general, including medical, food, and shelter assistance, as detailed elsewhere in this report, would help LGBT individuals as well (Gruberg, 2020).

Conclusion

LGBT individuals have been more likely to take steps to limit the spread of COVID—for example, 54% of the community is avoiding public transportation, 53% have purchased masks, and 27% have spoken to a doctor about the virus, compared to 44%, 43%, and 14% of the general population respectively (Human Rights Campaign Foundation, 2020d).

We should now take steps to actively support and include the community. An inclusive approach can help control COVID-19 more generally. For example, in light of blood shortages caused by the crisis, the FDA took steps to limit its rule that prohibited most MSM from giving blood. But MSM remain excluded if they have had a sexual encounter with any other man in the previous three months. Apart from imposing stigma on members of the LGBT community, such a ban harms the COVID-19 relief effort. Similarly, discrimination in healthcare settings makes it less likely that LGBT individuals will go in for testing, or if they do, that they will candidly engage in discussions regarding contact tracing that may out them to providers who do not know they are LGBT.

Members of the LGBT community survived the AIDS epidemic by relying on each other, by using protection to protect each other, and by taking community action without relying on the federal government. Drawing from these community norms by adopting LGBT-inclusive policies can teach us ways to bring COVID-19 under control as well. 🌟

Recommendations for Action

Federal government:

- Congress should ensure that organizations that provide direct relief and services, including LGBT organizations, are eligible for funding under CARES Act and future emergency support measures.
- Consistent with the Supreme Court's recent decision in *Bostock v. Clayton County*, HHS should issue a regulation affirming that Section 1557 of the Affordable Care Act prohibits discrimination based on sexual orientation and gender identity.
- Consistent with the Supreme Court's recent decision in *Bostock v. Clayton County*, HUD should withdraw its proposed rule reversing the Obama Administration's Equal Access Rule, which required that Housing and Urban Department programs, including certain shelters, were open to all eligible families and individuals "without regard to actual or perceived sexual orientation, gender identity, or marital status."
- HHS, DOJ, and other relevant agencies should clarify that the Religious Freedom Restoration Act and other religion-related protections do not justify discrimination against LGBT individuals.
- FDA should remove all vestiges of its ban on blood donation by men who have sex with men from its blood donation guidance, so that the LGBT community is not excluded from assisting in the COVID-19 relief effort.
- Congress should pass additional legislation along the lines of the CARES Act that expands measures that assist lower income individuals, including food stamp, unemployment, and related benefits.
- CDC should collect (and ask state and local agencies to collect) data regarding individuals' sexual orientation and gender identity. This

may, in part, be modeled on data collection in the National Health Interview Survey.

State governments:

- The appropriate state agencies and legislatures should fund community organizations including LGBT community centers, and ensure they are subject to protection against evictions and rent increases.
- State attorneys general should clarify that sex discrimination prohibitions in public accommodation discrimination, present in all 50 states, prohibit discrimination based on sexual orientation and gender identity, to ensure that LGBT individuals have access to essential services.
- The appropriate state agencies and legislatures should increase funding and support for homeless shelters, especially shelters dedicated to LGBT groups.
- The appropriate state entities should carry out Medicaid expansion.
- Governors and other authorized officers should clarify in emergency orders that LGBT focused services—including access to HIV medication and gender confirmation services—remain essential.
- State departments of education and school boards should require schools to provide support services via Zoom and other online outlets for LGBT students.
- State health departments should follow the lead of Pennsylvania and California in collecting data on sexual orientation and gender identity.

Local governments:

- Local agencies such as local school boards or public health departments should create safe virtual spaces and facilities for LGBT young people and seniors to engage with each other.
- Local health departments should develop programs that offer support to LGBT seniors.
- Local health departments should, where possible, rely on services and contracting with organizations that do not maintain moral or religious beliefs that promote sexual orientation or gender identity discrimination.
- Local health departments should provide resources such as COVID tests and the like to LGBT community centers.



About the Author

Professor Craig J. Konnoth teaches health law and LGBT rights at the University of Colorado School of Law where he also runs the health law program. His publications span health law and LGBT rights and have or will appear in the Harvard Law Review, the Yale Law Journal, and the Stanford Law Review, among others. He has filed several briefs in the U.S. Supreme Court on LGBT rights. He was California's Deputy Solicitor General, and worked at the Williams Institute at UCLA Law School, whose research on sexual orientation and gender identity is regularly relied on by policymakers and courts.

References

- Goldberg, S., & Wechsler, D. (2020). COVID-19 and LGBT Rights. In K. Pistor (Ed.), *Law in the Time of COVID-19* (pp. 99-108). New York: Columbia Law School.
- Gruberg, S. (2020). An Effective Response to the Coronavirus Requires Targeted Assistance for LGBTQ People. Retrieved July 27, 2020, from <https://www.americanprogress.org/issues/lgbtq-rights/news/2020/04/09/482895>
- Hensley-Clancy, M. (2020). Many Trans Students Have Been Forced To Hide Their True Selves Because Of College Closures. Retrieved July 27, 2020, from <https://www.buzzfeednews.com/article/mollyhensleyclancy/coronavirus-college-closures-trans-students>
- Human Rights Campaign Foundation (2020a). LGBTQ Intimate Partner Violence and COVID-19. Retrieved July 27, 2020, from https://assets2.hrc.org/files/assets/resources/IntimatePartnerViolence_062120.pdf
- Human Rights Campaign Foundation (2020b). The Economic Impact of COVID-19 Intensifies for Transgender and LGBTQ Communities of Color. Retrieved July 27, 2020, from <https://assets2.hrc.org/files/assets/resources/COVID19-EconImpact-Trans-POC-061520.pdf>
- Human Rights Campaign Foundation (2020c). The Impact of COVID-19 on Communities of Color. Retrieved July 27, 2020, from https://assets2.hrc.org/files/assets/resources/COVID_19_EconImpact-CommunitiesColor052020d.pdf
- Human Rights Campaign Foundation (2020d). The Economic Impact of COVID-19 on the LGBTQ Community (2020). Retrieved July 27, 2020, from <https://assets2.hrc.org/files/assets/resources/COVID19-EconomicImpact-IssueBrief-042220.pdf>
- Kornhaber, S. (2020). The Coronavirus Is Testing Queer Culture. Retrieved July 27, 2020, from <https://www.theatlantic.com/culture/archive/2020/06/how-quarantine-reshaping-queer-nightlife/612865/>
- Lang, N. (2020). Lawmakers Urge Trump Administration to Collect Data on LGBTQ COVID-19 Patients. Retrieved July 27, 2020, from <https://www.nbcnews.com/feature/nbc-out/lawmakers-urge-trump-administration-collect-data-lgbtq-covid-19-patients-n1211641>
- SAGE USA (2020). LGBTQ Older People & COVID-19. Retrieved July 27, 2020, from <https://www.sageusa.org/wp-content/uploads/2020/05/2020-lgbtq-older-adults-covid.pdf>
- The Fenway Institute (2020). Coronavirus, COVID-19, and Considerations for People Living with HIV and LGBTQIA+ People. Retrieved July 27, 2020, from https://fenwayhealth.org/wp-content/uploads/C19MC-9_COVID-19and-LGBTQIA-and-People-Living-with-HIV-Brief_final2_links.pdf
- The Trevor Project (2020). Implications of COVID-19 for LGBTQ Youth Mental Health and Suicide Prevention. Retrieved July 27, 2020, from <https://www.thetrevorproject.org/2020/04/03/implications-of-covid-19-for-lgbtq-youth-mental-health-and-suicide-prevention/>
- Velasco, G., & Langness, M. (2020). COVID-19 Action that Centers Black LGBTQ People Can Address Housing Inequities. Retrieved July 27, 2020, from <https://www.urban.org/urban-wire/covid-19-action-centers-black-lgbtq-people-can-address-housing-inequities>
- Whittington, C., Hadfield, K., & Calderón, C. (2020). The Lives & Livelihoods of Many in the LGBTQ Community are at Risk amidst the COVID-19 Crisis, The Human Rights Campaign. Retrieved July 27, 2020, from <https://assets2.hrc.org/files/assets/resources/COVID19-IssueBrief-032020-FINAL.pdf>

Immigration Law's Adverse Impact on COVID-19

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SUMMARY. Immigration law has played a large and deleterious role during the pandemic. In early 2020, the Trump administration relied on the Immigration and Naturalization Act to bar entry of non-nationals from affected areas. Once the pandemic spread widely in the United States, the administration imposed broad restrictions on immigration, including blocking entry at land borders, effectively overriding asylum laws. While furthering the administration's pre-pandemic, anti-immigration agenda, these measures did little to keep the virus out of the country, or reduce its impact. Immigrants have also suffered disproportionately from COVID-19 due to numerous factors, including high rates of employment as essential workers, substandard housing, and immigration-based restrictions on non-citizens' access to public benefits, including Medicaid. The recently promulgated public charge rule, plus ongoing immigration enforcement activities and anti-immigrant rhetoric, have compounded these vulnerabilities, leaving many immigrants afraid to access health care or interact with public health workers. SARS-COV-2 (the virus responsible for COVID-19) has also spread widely in immigration facilities, where detainees are unable to practice social distancing and lack access to adequate hygiene and health care.

Introduction

Since the 19th century, immigration law has authorized the exclusion of immigrants with communicable diseases. These exclusions, grounded in racist and eugenicist conceptions of disease, have done little to protect the public's health, while immigration laws that limit immigrants' access to public benefits have left immigrants more vulnerable to communicable diseases.

Immigration law's potential to adversely affect public health has been clearly evident during the current pandemic. Initially, the Trump administration used its immigration powers to deny entry to non-U.S. nationals traveling first from China and then other countries. The administration credited these bans with stopping the virus, but they only offered the illusion of containment. Further, within the United States, restrictionist immigration laws and policies magnified the vulnerability of immigrants as well as their families and communities.

Using the Pandemic as a Pretext for Restricting Immigration

The initial federal response to the pandemic relied heavily on immigration-based restrictions. On January 31, 2020, the same day that the secretary of Health and Human Services (HHS) declared COVID-19 a public health emergency, President Trump used Sections 212(f) and 215(a) of the Immigration and Naturalization Act (INA) to bar entry into the United States by most non-nationals who had been "physically present within the People's Republic of China" 14 days prior to their arrival in the United States. Although

the president has pointed to this ban as evidence that he took aggressive measures to protect the nation from the pandemic, the order was riddled with exceptions. Most importantly, it did not apply to U.S. nationals returning from China. Although this allowed citizens and legal permanent residents to return home, it also undermined the ban's supposed goal, as over 430,000 individuals entered the United States from China, including nearly 40,000 in the two months following the ban (Eder et al., 2020). The ban also did not prevent people traveling from other countries from bringing SARS-COV-2 into the United States.

By relying on the INA and basing travel restrictions on nationality rather than exposure, the "China ban" seemed to reflect and reassert the erroneous belief that non-nationals are riskier than Americans. This false equation of risk with nationality was also evident in several other orders issued by the president in the winter and spring of 2020. For example, on February 29, the president used his immigration powers to ban entry (with exceptions similar to those included in the China ban) to non-U.S. nationals who had been in Iran in the past 14 days. On March 11, a similar ban was extended to non-U.S. nationals who had been in the Schengen Area of the European Union. The hurried and unclear implementation of this order led thousands of Americans, who feared the ban would be extended to them, to rush home, only to be forced to wait for hours in overcrowded, chaotic and potentially infectious conditions at U.S. customs lines (Miller et al., 2020). Despite that chaos, the president banned non-national travelers from the United Kingdom on March 14, and from Brazil on March 24.

The travel bans, which potentially conflict with the International Health Regulations by exceeding the World Health Organization's guidance, were not the only pandemic response that seemed more designed to further the administration's anti-immigration agenda than protect public health. On April 22, the president ordered a 60-day ban on the issuance of legal permanent resident visas. That ban was largely symbolic; it contained numerous exceptions and had little impact because most consulate and immigration offices overseas were temporarily closed in March. However, pointing to the pandemic's impact on the labor market, on June 22, the president extended the ban for the rest of the year, and expanded it to include non-immigrant H-1B and H-2B visas. The president also directed the HHS secretary to provide guidance "for implementing measures that could reduce the risk that aliens seeking admission or entry to the United States may introduce, transmit, or spread SARS-COV-2 within the United States."

Even prior to that directive, the Centers for Disease Control and Prevention (CDC) relied on the Public Health Services Act to restrict entry by non-nationals. On March 20, CDC issued an interim final rule under 42 U.S.C. § 265 that amended the federal quarantine regulations to allow CDC to bar non-nationals from any country that it designated as having a communicable disease from which there is a "serious danger of the introduction of such communicable disease into the U.S." In contrast to the CDC's pre-existing quarantine regulations, the new rule, codified at 42 CFR 71.40, does not require any individualized assessment of risk; nor is it limited to quarantinable diseases. It also applies only to non-U.S. nationals, allowing CDC to base health decisions on nationality, rather than epidemiology.

Using this new rule, on March 26, CDC barred non-nationals from entering the United States from Mexico and Canada. Although the bar was originally set to lapse after 30 days, CDC extended it until it determined that COVID-19 is no longer a serious danger to the United States. Relying on that order, U.S. Customs and Border Patrol (USCBP) has been expelling immigrants at the southern border, including unaccompanied minors and asylum-seekers. The ACLU has filed a federal lawsuit challenging this practice as an evasion of the nation's asylum laws.

Critically, although Mexico now faces a significant outbreak, this was not the case when CDC first barred entry of non-U.S. nationals at land borders from Mexico (Rios, 2020). In addition, throughout the pandemic, the administration has continued to deport non-citizens, including individuals infected with COVID-19, thereby helping to spread the disease to nations that have fewer resources to contain the pandemic (Gallón, 2020).

Immigration Law's Incidental Impact on COVID-19

In 2017, more than 40,000,000 individuals living in the United States were born in another country. Forty-five percent of immigrants are naturalized citizens; less than a quarter are unauthorized (Pew Research Center, 2020). Although the immigrant population is very heterogeneous, immigrant communities (which include legal and undocumented immigrants, naturalized citizens, and families of members of immigrants) have been especially hard hit by COVID-19. For example, the heavily immigrant community

of Chelsea, Massachusetts, had the highest rates of infection in that state (Barry, 2020). Immigrants also comprise a large share of the workforce in many of the meatpacking plants that have experienced significant outbreaks (Jabour, 2020).

This should not be surprising. Even before the pandemic, laws regulating immigrant's rights within the United States served as an adverse social determinant of health by limiting non-citizens' employment opportunities and access to a wide array of public benefits (Dondero & Altman, 2020). In the present pandemic, immigrant communities have also faced heightened risk due to high levels of employment in "essential services," overcrowded housing, and language barriers to receiving public health messages. In addition, as COVID-19 struck the United States, the federal government was seeking to limit immigration, build a wall on the southern border, and end the Deferred Action for Childhood Arrivals (DACA) program (which was granted at least a temporary reprieve by the Supreme Court's June 18, 2020 decision in *Department of Homeland Security v. Regents of the University of California*). These initiatives, plus heated, frequently racially charged, anti-immigration rhetoric from the president and public officials helped to sow a climate of fear among immigrants.

Even before the Trump administration, federal laws limited non-citizens' access to health and other public benefits. Under the 1996 Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA), undocumented immigrants (including DACA recipients) are "unqualified" for federally-funded health benefits, except emergency Medicaid. Most lawfully present non-citizens are also ineligible for covered benefits for the first five years they have that status. PRWORA also allows states to further restrict coverage, or use their own funds to cover additional classes of non-citizens, including undocumented immigrants. Subsequent federal laws have given states the option to cover, with federal support, lawfully present children and pregnant people in Medicaid and the Children's Health Insurance Program (CHIP). According to Medha Makhoul, in 2019, 34 states offer Medicaid, and 23 offer CHIP to lawfully residing children. Twenty-five states cover lawfully residing pregnant women; 16 states also cover undocumented pregnant people. Six states cover some classes of non-citizens through state-funded programs (Makhoul, 2020). Lawfully present non-citizens can also access coverage and receive premium support to purchase insurance on the state and federal exchanges established under the Affordable Care Act (ACA). The ACA, however, maintains PRWORA's limitations on non-citizens' eligibility for Medicaid and CHIP.

As a result of the restrictions on coverage, as well as the fact that non-citizens are less likely than citizens to work for employers that provide insurance, in 2018, non-citizens were "significantly more likely to be uninsured than citizens" (KFF, 2020). Among the non-elderly population, 23% of lawfully present immigrants and more than 40% of undocumented immigrants were uninsured, as compared to less than 10% of citizens (KFF, 2020).

The Trump administration's new public charge rule creates additional barriers to health insurance and other public benefits for non-citizens. Under the INA, most non-citizens (excluding refugees and others granted humanitarian relief) must show that

they are “not likely to become a public charge” in order to gain entry into the United States or receive legal permanent resident status. Previously, receipt of non-cash benefits, other than for long-term care, did not factor into the public charge determination. However, on August 14, 2019, the U.S. Citizenship and Immigration Services (USCIS) issued its long-awaited public charge rule, which defines a “public charge” as a non-citizen who receives cash benefits, non-Emergency Medicaid, Supplemental Nutrition Assistance, or housing benefits for 12 out of 36 months. Past receipt of these benefits (excluding Medicaid for pregnant people and children) are treated as heavily weighted negative factors when USCIS determines if a non-citizen is likely to become a public charge in the future. In its comments in the Federal Register accompanying the original proposed rule (which differed from the final version in several key respects) in October 2019, USCIS conceded the rule would lead to increased spread of communicable diseases.

Shortly after the final public charge rule was published, several states and advocacy organizations sought to enjoin it. Although at least five lower courts granted preliminary injunctions finding that USCIS had likely exceeded its authority, on January 27, the Supreme Court allowed the rule to go forward. On February 24, just before the pandemic struck the United States, USCIS began enforcement (Parmet, 2020). On April 24, the Supreme Court rejected a petition by New York’s attorney general to block the rule due to its potentially adverse impact during the pandemic.

Nevertheless, in response to the pandemic, on March 13, USCIS announced that it would not “consider testing, treatment, nor preventive care (including vaccines, if a vaccine becomes available) related to COVID-19 as part of the public charge inadmissibility determination” even if they were paid for by public benefits. The guidance also stated that immigrants who lost their jobs due to the pandemic could submit evidence to that effect for their public charge determination. This guidance, however, did not apply to other health care-related expenses. Nor did USCIS suspend the operation of the already confusing rule. On July 29, a federal judge in the Southern District of New York issued a nationwide injunction citing the pandemic. The Administration will likely appeal that order.

Immigration enforcement adds an additional barrier to care. Although Immigration and Custom Enforcement (ICE) considers hospitals and clinics to be sensitive locations in which enforcement actions will not ordinarily be conducted, clinicians have reported that fear of ICE has led patients to forgo appointments and care (Parmet, 2020). It seems likely that this fear may also discourage cooperation with contact tracing.

Many non-citizens have also been denied access to some of the supports Congress established in response to the pandemic. Most importantly, the \$1,200 cash assistance provided under the Coronavirus Aid, Relief and Economic Security (CARES) Act was limited to citizens and immigrants who file taxes using a Social Security, rather than taxpayer identification number. Several lawsuits have challenged the law as discriminating against the citizen children and spouses of undocumented workers. To date,

no court decisions have been reported. Undocumented workers are also unable to access unemployment compensation provisions provided by the Families First Coronavirus Response Act.

Another example of how policies grounded in immigration law can harm the health of non-citizens and citizens alike is the July 6 decision by the White House not to extend an exemption put in place in the spring that allowed international students to stay in the United States if their courses were entirely online. By refusing to permit students to remain in the country if their classes are online, the Administration is pushing universities to open, even if they cannot do so safely. “This could have jeopardized the health of students, faculty, and staff, as well as university communities. After several universities and states attorney generals filed suit, USCIS reversed its decision on July 14.

Immigration Detention

Immigration detention has created an additional health risk. Thousands of immigrants are detained in detention centers in border states, or local jails and prisons throughout the country.

Even before the pandemic, many detention facilities were unhygienic and overcrowded, allowing for the spread of contagious diseases such as influenza (Parmet, 2020). Given the close quarters and poor conditions, it is not surprising that SARS-COV-2 has spread widely in many detention facilities. As of May 23, 2020, more than 1,400 detainees and 44 employees had tested positive (Erfani et al., 2020). Given ICE’s relative lack of transparency about its testing results and policies, those numbers could be even higher.

In a positive move, ICE has reduced the population of detainees by nearly 30% (ICE’s goal is to reduce the population by 75%) and has worked with CDC to establish guidelines that call for social distancing, improved hygiene, and isolation and care for detainees who test positive (Erfani et al., 2020). Nevertheless, hundreds if not thousands of detainees have gone to federal court (usually seeking a writ of habeas corpus) arguing that their continued detention violates the Fifth Amendment. In response, several courts have ordered the release of petitioners who, because of their age or preexisting medical conditions, were at heightened risk for COVID-19. Courts have also ordered detention facilities to comply with CDC guidelines. Many courts, however, have rejected petitions from detainees who do not face any special risk. As the federal court in the Middle District of Pennsylvania explained in *Saillant v. Hoover* on April 16, (a case involving an ICE detainee held in a Pennsylvania prison) it is “not enough for a petitioner to allege that he is detained and presented with a risk of contracting COVID-19 that is common to all prisoners.”

Litigation has also centered on outbreaks in family detention centers. On June 26, in *Flores v. Barr*, federal Judge Dolly M. Gee of the Central District of California, who oversees the 1997 Flores Settlement that governs the treatment of minors in custody, stated that “family residential centers are on fire” and ordered the release of all children who had been in custody for more than 20 days by July 17.

Assessment

Immigration law has been employed by the administration as a response to the pandemic; it also has had an indirect impact on pandemic within the United States. In both cases, the impact has been largely negative. Several months into the pandemic, it is apparent that nationality-based travel restrictions and immigration bans have not protected the United States from COVID-19. If anything, they have reinforced the false belief that the pandemic can be kept out by keeping out non-nationals. In addition, by denying non-citizens access to health and other benefits, detaining thousands of people in close and unsanitary conditions, and creating fear and distrust in immigrant communities, immigration laws and policies have increased the vulnerability of non-citizens and their families to COVID-19. 🦠

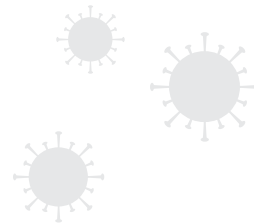
Recommendations for Action

Federal government:

- The federal government should base travel bans on epidemiological factors, rather than nationality or immigration status.
- CDC should repeal its new interim final rule and base exclusion orders on the risk presented by travelers rather than their nationality. CDC's orders should not be used to override asylum laws.
- ICE should declare that it will not enforce immigration laws within any health care facility, and that it will not use any information obtained from health or public health workers, including from contact tracers. This declaration should be widely messaged, in multiple languages, to immigrant communities.
- USCIS should repeal the public charge rule, or at least, suspend it for the duration of the pandemic. If USCIS does not act, Congress should repeal the rule.
- ICE should suspend immigration raids during the pandemic, except where they are necessary to prevent an imminent risk to public safety. A pandemic is not the time to add to fear and distrust in immigrant communities.
- ICE should further depopulate immigration detention facilities, holding only immigrants who pose an immediate risk to public safety. ICE should ensure that detainees who remain receive language-appropriate health information, adequate health care, and the means to practice good hygiene and social distancing.
- ICE should cease deporting individuals who are infected with COVID-19.

State governments:

States should provide Medicaid and CHIP to all otherwise eligible non-citizens. States should also use their own funds to provide coverage to additional classes of non-citizens.



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References

- Barry, E. (2020). In a Crowded City, Leaders Struggle to Separate the Sick from the Well. *New York Times*. April 28, retrieved July, 14, 2020, from <https://www.nytimes.com/2020/04/25/us/coronavirus-chelsea-massachusetts.html>
- Dondero, M., & Altman, C. (2020). Immigrant policies as health policies: State immigrant policy climates and health provider visits among U.S. immigrants. *SSM - Population Health*. 10(2020) 100559, 1-11.
- Eder, S., Fountain, H., Keller, M. H., Xiao, M., & Stevenson, A. (2020). 430,000 People Have Traveled from China to U.S. Since Coronavirus Surfaced. *New York Times*. Retrieved July 14, 2020, from <https://www.nytimes.com/2020/04/04/us/coronavirus-china-travel-restrictions.html?action=click&module=Spotlight&pgtype=Homepage>
- Erfani, P., Lee, C., Uppal, N., & Peeler, K. (2020). A Systematic Approach to Mitigate the Spread of COVID-19 in Immigration Detention Facilities. *Health Affairs Blog*. Retrieved July 14, 2020, from <https://www.healthaffairs.org/doi/10.1377/hblog20200616.357449/full>
- Gallón, N. (2020). 44 Migrants on One US Deportation Flight Tested Positive for Coronavirus. *CNN*. Retrieved July 14, 2020, from <https://www.cnn.com/2020/04/17/americas/us-migrants-guatemala-coronavirus/index.html>
- Jabour, A. (2020). Immigrant Workers have Borne the Brunt of Covid-19 Outbreaks at Meatpacking Plants. *Washington Post*. Retrieved July 14, 2020, from <https://www.washingtonpost.com/outlook/2020/05/22/immigrant-workers-have-born-brunt-covid-19-outbreaks-meatpacking-plants/>
- Kaiser Family Foundation (KFF)(2020). *Health Coverage of Immigrants*. Retrieved July 14, 2020, from <https://www.kff.org/disparities-policy/fact-sheet/health-coverage-of-immigrants/>
- Malkouf, M. D. (2020). Laboratories of Exclusion, Medicaid, Federalism & Immigrants. *N.Y.U. Law Review* (forthcoming). Retrieved July 14, 2020, from <https://ideas.dickinsonlaw.psu.edu/cgi/viewcontent.cgi?article=1143&context=fac-works>
- Miller, G., Dawsey, J., & Davis, A. C. (2020). One Final Viral Infusion: Trump's Move to Block Travel from Europe Triggered Chaos and a Surge of Passengers from the Outbreak's Center. *Washington Post*. Retrieved July 14, 2020, from https://www.washingtonpost.com/world/national-security/one-final-viral-infusion-trumps-move-to-block-travel-from-europe-triggered-chaos-and-a-surge-of-passengers-from-the-outbreaks-center/2020/05/23/6-4836a00-962b-11ea-82b4-c8db161ff6e5_story.html
- Parmet, W. E. (2020). Trump's Immigration Policies will make the Coronavirus Pandemic Worse. *STAT News*. Retrieved July 14, 2020, from <https://www.statnews.com/2020/03/04/immigration-policies-weaken-ability-to-fight-coronavirus/>
- Pew Research Center (2020). *Key Findings About U.S. Immigrants*. Retrieved July 13, 2020, from <https://www.pewresearch.org/fact-tank/2019/06/17/key-findings-about-u-s-immigrants/>
- Ríos, A. M. (2020). COVID-19 Cases and Deaths 2020. *Statista*. Retrieved July 14, 2020, from <https://www.statista.com/statistics/1107063/mexico-covid-19-cases-deaths/>

Protecting the Rights of People with Disabilities

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SUMMARY. One in four Americans – a diverse group of 61 million people – experience some form of disability (Okoro, 2018). On average, people with disabilities experience significant disparities in education, employment, poverty, access to health care, food security, housing, transportation, and exposure to crime and domestic violence (Pendo & Iezzoni, 2019). Intersections with demographic characteristics such as race, ethnicity, gender, and LGBT status, may intensify certain inequities. For example, women with disability experience greater disparities in income, education, and employment (Nosek, 2016), and members of underserved racial and ethnic groups with disabilities experience greater disparities in health status and access to health care (Yee, et. al, 2016). These longstanding inequities are compounded by the COVID-19 pandemic and by governmental and private responses that discriminate on the basis of disability. Legal protections of people with disabilities are governed by two key federal laws: the Americans with Disabilities Act of 1990 (ADA) and Section 504 of the Rehabilitation Act (“Section 504” or “Rehabilitation Act”). Together, these laws ensure that people with disabilities have equal opportunities in employment, in state and local services and programs, and to goods and services. The broad reach of these laws impact a host of issues raised by the COVID-19 pandemic. Enforcing agencies have provided COVID-19-specific guidance on the application of the laws in health care and in employment. However, gaps in protections as well as widespread lack of knowledge of and noncompliance with the ADA and the Rehabilitation Act limit their impact. Recommendations include: continued enforcement of the laws; clear and current agency guidance on how to comply with the laws; education about the requirements of the laws, especially in health care settings; and improved data collection and reporting.

The Americans with Disabilities Act

The ADA was enacted to address widespread discrimination against people with disabilities. The law provides a clear national mandate for eliminating discrimination and ensuring equal opportunities in all arenas of American life. It prohibits discrimination based on disability in employment (Title I), public programs, services, and activities (Title II), public transportation and places of public accommodations (businesses generally open to the public) (Title III), and telecommunications (Title IV). The ADA expands the protections of the Rehabilitation Act, an earlier federal statute that prohibits disability discrimination in federal employment and in programs and activities that receive federal financial assistance. The laws have similar requirements, and courts have used cases under the Rehabilitation Act to assist in interpreting the ADA.

The ADA has two features that distinguish it from other civil rights laws. First, only individuals with a disability as defined in the ADA are protected.

Congress amended the ADA in 2008 to clarify that the statutory definition of disability should be construed in favor of broad coverage of individuals. Disabilities are diverse, and can be physical, sensory, cognitive, intellectual or developmental. Mental health conditions, substance use disorder, and chronic illness can also be disabilities. Underlying health conditions that put individuals at greater risk of severe illness from COVID-19 such as lung disease, serious heart conditions, immune-suppressing conditions, and diabetes would be considered disabilities in virtually all cases. A longer-term or symptomatic case of COVID-19 would be considered a disability if has a substantial impact on a major life activity, such as breathing.

Second, beyond simply prohibiting disability-based discrimination, the ADA imposes an affirmative obligation to ensure that people with disabilities have equal opportunities. For example, Title I requires employers to provide reasonable accommodations, which are changes to the way a job is done or to the work environment that allow an employee to do their job. Under Title II, state and local governments make reasonable modifications to ensure

people with disabilities have an equal opportunity to participate in or receive the benefits of services, programs, or activities. Businesses must comply with similar requirements to ensure full and equal enjoyment of their goods and services under Title III. Reasonable modification might include, for example, an exception to a state, local, or retailer policy requiring masks for individuals with disabilities that make it difficult or inadvisable to wear masks (Pendo, et. al. 2020).

The ADA's broad reach means that it applies to a host of issues raised by the COVID-19 pandemic, many of which are addressed in other Chapters. This Chapter will focus on two critical areas that impact the diverse population of people with disabilities: access to health care and protections in the workplace.

Health Care

The Impact of COVID-19 on Disability Access to Health Care

People with disabilities are at higher risk for COVID-19 infection and serious disease because of pre-existing disparities in health status, access to health care, and other social determinants of health (Pendo & Iezzoni, 2019). They have higher rates of underlying health conditions (Garg, 2020) and are more likely to live in nursing homes and other congregate living situations (Okoro, 2018). People with disabilities may be less able to take protective measures against the spread of COVID-19. For example, some disabilities make it difficult or inadvisable to wear a mask, and reliance on direct care workers — many of whom do not have access to personal protective equipment — may preclude physical distancing (Drum, 2020). However, we do not have a clear national picture of the number of disability-related COVID-19 infections or deaths because that data is not consistently collected.

People with disabilities have well-founded concerns of discrimination and unequal treatment if they do seek health care services related to COVID-19, as research shows that people with disabilities experience significant disparities in health outcomes and access to health care (Pendo & Iezzoni, 2019). For example, in response to the burden placed on our health care system by COVID-19, states and health care facilities are developing medical scarce resource allocation policies to determine how to allocate critical health care resources when there is not enough capacity to treat all patients (see Chapter 24). Disability advocates and organizations have raised serious concerns about the impact of medical allocation policies that explicitly and implicitly exclude, disadvantage, or otherwise discriminate on the basis of disability. Concerns have also been raised regarding lack of effective communication with patients with disabilities (such as patients who are Deaf or hearing impaired) and hospital visitor policies that exclude direct care workers and others who provide needed assistance and support.

Legal Response to Health Care Policies

The ADA prohibits exclusion of or discrimination against people with disabilities in health care in state policies and health care services offered by public hospitals (Title II), and in private physician's offices and private hospitals (Title III). Section 1557

THE ADA PROTECTS INDIVIDUALS WHO HAVE:

- a) a physical or mental impairment that substantially limits one or more major life activities,
- b) a record of such an impairment, or
- c) are regarded as having such an impairment.

of the Patient Protection and Affordable Care Act (ACA) amends the Rehabilitation Act to provide additional protections against discrimination in health care. These laws require: physical access to health care services and facilities, including accessible spaces and the removal of barriers; effective communication, including auxiliary aids and services such as the provision of sign language interpreters or materials in alternative formats; and reasonable modification of health care policies, practices, and procedures when necessary to accommodate individual needs.

The U.S. Dept. of Justice (DOJ) is charged with the enforcement of Section 504 and Titles I, II, and III of the ADA. The U.S. Dept. of Health and Human Services (HHS) Office for Civil Rights (OCR) is also responsible for enforcing Title II of the ADA, the Rehabilitation Act, and Section 1557 of the ACA with respect to health care. These agencies issued regulations and guidance regarding the requirements of these laws in various health care settings prior to COVID-19, and OCR recently has provided specific guidance on the application of these laws to health care policies (Ctr. For Pub. Representation, 2020).

Medical Scarce Resource Allocation Policies and Crisis Standards of Care Protocols. On March 28, 2020, OCR issued a bulletin on the application of federal disability rights laws to medical scarce resource allocation policies (Ctr. For Pub. Representation, 2020). The bulletin reaffirms that these laws, like other civil rights laws, remain in effect during the pandemic. It also provides:

"... [P]ersons with disabilities should not be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative "worth" based on the presence or absence of disabilities or age. Decisions by covered entities concerning whether an individual is a candidate for treatment should be based on an individualized assessment of the patient based on the best available objective medical evidence."

The bulletin also emphasizes legal requirements including the obligation to ensure effective communication with individuals who are Deaf, hard of hearing, blind, have low vision, or have speech disabilities, and to make reasonable modifications to address the needs of individuals with disabilities.

As of July 1, OCR has resolved three complaints about medical scarce resource allocation policies, which provide specific guidance about what types of provisions constitute discrimination. One settlement, for example, was reached after Tennessee removed categorical exclusions based on disability or resource

intensity, consideration of long-term survivability, or reallocation of personal ventilators from its allocation plan, and added the requirement of reasonable modifications to assessment tools (such as Sequential Organ Failure Assessment scores)(Ctr. For Pub. Representation, 2020)(see Chapter 24).

Hospital Visitor Policies. OCR also resolved a complaint after Connecticut issued an executive order regarding non-visitation policies for short-term hospitals, outpatient clinics, and outpatient surgical facilities to ensure that people with disabilities are not denied reasonable access to needed support persons.

Assessment

OCR has provided clear guidance that medical allocation and other policies that explicitly and implicitly exclude, disadvantage, or otherwise discriminate on the basis of disability violate federal nondiscrimination laws. A coalition of disability rights organizations published a document and evaluation framework that provides additional advice on how states, health care institutions, and health care providers can make reasonable modifications to policies and practices to avoid disability discrimination (Ctr. For Pub. Representation, 2020).

However, reports of disability bias and discrimination persist and there is evidence of widespread pre-existing lack of knowledge of and noncompliance with the ADA and the Rehabilitation Act in the health care setting (Pendo & Iezzoni, 2019). Lack of knowledge is complicated by misrepresentation of the law in other contexts. For example, some anti-mask activists encourage their followers to falsely represent themselves as disabled to avoid mask requirements. There are reports of official-looking flyers or identification cards with statements regarding the ADA and mask requirements. The DOJ issued a statement in response, COVID-19 ALERT: Fraudulent Face Mask Flyers, clarifying that the documents were not issued or endorsed by the Department.

Finally, we lack data related to COVID-19 testing, infections, and outcomes for people with disabilities. As with other disproportionately impacted groups, data is needed to assess risks for people with disabilities, to develop health protection measures, and to identify and address important disparities. There are data collection standards for disability status that could be used for federal, state, and local collection and reporting of COVID-19 data. The ACA already requires all federally conducted or supported health care and public health programs to collect data on disability status using, at a minimum, the six disability questions in the American Community Survey used to gauge disability among the U.S. population (Pendo & Iezzoni, 2019).

Employment

The Impact of COVID-19 on Workers with Disabilities

A disproportionate number of people with disabilities have lost jobs due to COVID-19, compounding pre-existing disparities in employment and economic security (Global Disability Inclusion, 2020). Workplaces are also impacted by new health and safety concerns, and many have instituted new workplace policies to reduce the risk of exposure. Some employer responses to COVID-19

greatly benefit the reported 30% of the workforce with a disability, such as flexible and remote work programs (Jain-Link & Kennedy, 2020). Other responses have the potential to disproportionately impact people with disabilities, such as COVID-19 screening and testing regimes that unnecessarily reveal disability-related information (such as the presence of underlying health conditions).

Legal Guidance on Employment Practices and Policies

Title I of the ADA requires employers with 15 or more employees to avoid discrimination in terms, conditions, and privileges of employment, and to provide reasonable accommodation of qualified individuals with a disability within certain limits. It also limits the collection of medical and disability-related information in the workplace in order to reduce the potential for disability-based bias and discrimination. The U.S. Equal Employment Opportunity Commission (EEOC) is responsible for enforcement of Title I of the ADA, and has provided specific and current guidance on the application of the ADA in light of COVID-19 (EEOC, 2020).

COVID-19 Screening and Testing. The ADA limits medical exams and disability inquiries in the workplace to ensure people with disabilities are assessed on merit, rather than the presence or absence of disability, while protecting the rights of employers to make sure that employees can perform their jobs safely. The law creates three categories of medical inquiries and exams by employers. Before an offer is made, an employer is generally prohibited from asking disability-related questions or requiring medical exams. After an offer is made, the employer can request medical information and require exams as a condition of starting work as long as it does so for all entering employees in the same job category. During employment, an employer may request medical information and require exams that are “job-related and consistent with business necessity,” for example where the employee may pose a “direct threat” (a significant risk of substantial harm to the health or safety of the employee or others, which cannot be eliminated or reduced by a reasonable accommodation).

According to the EEOC, screening and testing of employees for COVID-19 is permitted under the ADA because an employee with the virus poses a direct threat to health and safety (EEOC, 2020). Consistent with current CDC guidance, reliable and accurate testing measures such as taking temperatures, asking about symptoms, or testing employees for present infection with the virus that causes COVID-19 are permitted under the ADA. However, the CDC currently recommends against using tests for COVID-19 antibodies (evidence of past infection with the virus that causes COVID-19) to make decisions about returning employees to the workplace. Accordingly, antibody test requirements are not allowed under the ADA (EEOC, 2020).

Employers must maintain the confidentiality of any medical information they receive. Confidentiality requirements do not prevent employers from complying with directions from the CDC or other public health authorities. For example, an employer may disclose the name of an employee who has COVID-19 to a public health agency (but not to the workplace generally, or to the public absent consent from the infected individual)(EEOC, 2020).

Reasonable Accommodations. The ADA requires employers to provide reasonable accommodations that allow a disabled employee to do their job. Employers do not have to provide accommodations that pose an undue hardship (involving significant difficulty or expense) or a direct threat. For example, an employer can require an employee to stay home if the employee tests positive for COVID-19 or has COVID-19 symptoms. However, the employer should consider whether the direct threat can be minimized through a reasonable accommodation that allows the employee to stay on the job, such as working remotely. Employers must also consider reasonable accommodations for individuals who are at increased risk of COVID-19 due to underlying health conditions that meet the ADA definition of disability.

Employers are not required to provide ADA accommodations to employees without disabilities who are at increased risk of COVID-19 due to a reason other than disability (such as age or ordinary pregnancy) or to employees without disabilities who are related to someone at increased risk due to disability (such as a child with an underlying medical condition). Of course, an employer may choose to accommodate these workers (EEOC, 2020).

Assessment

The EEOC has provided specific, regularly-updated guidance on the application of the ADA to the workplace in light of COVID-19. The EEOC's guidance has raised awareness of the ADA and its protections as non-essential businesses begin to reopen.

There is also evidence that employer attitudes toward remote working have shifted as a result of COVID-19. Prior to COVID-19, many employers and courts were reluctant to allow working remotely as a reasonable accommodation. Now, major employers report that they will continue to let employees work remotely after workplaces reopen.

However, there are significant gaps in the ADA's protections. Not all jobs can be done remotely, and not all employees who are at risk or have family members who are at risk are entitled to work remotely. Although some employers are accommodating more employees that required by the ADA, others are not. There is also confusion about the interaction of the ADA with other workplace laws and policies regarding leave. 🦠

Recommendations for Action

Federal government:

- OCR should continue to enforce and provide COVID-specific guidance on the requirements of the ADA, Rehabilitation Act, and Section 1557 for health care providers, institutions, and systems regarding medical allocation policies, hospital visitor policies, and other policies that impact care for people with disabilities.
- Congress should require HHS to collect and publicly report standardized data related to COVID-19 testing, infections, treatment, and outcomes including data disaggregated by disability status using data collection standards for disability that have been developed under the ACA.
- The EEOC is providing clear, timely, and COVID-specific guidance on the requirements of the ADA in the workplace. The DOJ should provide similar guidance on the requirements of the ADA and Rehabilitation Act in COVID-related policies adopted by state, local, and retail and other business entities, including mask-wearing policies.

State governments:

- State agencies should enforce and provide COVID-specific guidance on the requirements of state laws that prohibit discrimination based on disability.
- States should review and revise state and local policies related to COVID-19, including medical scarce resource allocation policies, hospital visitor policies, and mask-wearing policies, to ensure that they comply with requirements of federal disability rights law.
- Pursuant to federal direction or on their own initiative, states should require the collection and public reporting of standardized data related to COVID-19 testing, infections, treatment, and outcomes including data disaggregated by disability status, using data collection standards for disability that have been developed under the ACA.
- States should adopt policies that encourage employers to allow all employees to work remotely where possible, regardless of disability.

Local governments:

- Local governments should review and revise local policies related to COVID-19, including mask-wearing policies, to ensure that they comply with requirements of federal disability rights law.
- Pursuant to federal or state direction or on their own initiative, local governments should require the collection and public reporting of standardized data related to COVID-19 testing, infections, treatment, and outcomes including data disaggregated by disability status, using data collection standards for disability that have been developed under the ACA.
- Local governments should adopt policies that encourage employers to allow all employees to work remotely where possible, regardless of disability.



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References

- Americans with Disabilities Act of 1990, 42 U.S.C. § 12101 et seq., amended by Americans with Disabilities Amendments Act of 2008, Pub. L. No. 110-35, 122 Stat. 3553 (2008).
- Center For Public Representation (2020). COVID-19 Medical Rationing & Hospital Visitor Policies. Retrieved July 17, 2020, from <https://www.centerforpublicrep.org/covid-19-medical-rationing/>.
- Drum, C.E., Oberg, A., Cooper, K., & Carlin, R. (2020). COVID-19 & Adults with Disabilities: Health and Health Care Access Online Survey Summary Report. Retrieved July 17, 2020, from https://www.aahd.us/wp-content/uploads/2020/05/COVID-19_Summary_Report.pdf
- Garg, S. (2020). Hospitalization Rates and Characteristics of Patients Hospitalized with Laboratory-Confirmed Coronavirus Disease 2019—COVID-NET, 14 States, March 1–30, 2020. *Morbidity and Mortality Weekly Report*, 69(15), 458–464.
- Global Disability Inclusion (2020). Survey Reports People with Disabilities Are More Negatively Affected by The Economic Impact of COVID-19. Retrieved July 17, 2020, from <https://www.prnewswire.com/news-releases/global-disability-inclusion-survey-reports-people-with-disabilities-are-more-negatively-affected-by-the-economic-impact-of-covid-19-301052873.html>
- Jain-Link, P. & Kennedy J.T. (2020). Why People Hide Their Disabilities at Work. Retrieved July 17, 2020, from <https://hbr.org/2019/06/why-people-hide-their-disabilities-at-work>
- Nosek, M. A. (2016). Health Disparities and Equity: The Intersection of Disability, Health, and Sociodemographic Characteristics among Women. In S. E. Miles-Cohen & C. Signore (Eds.), *Eliminating Inequities for Women with Disabilities: An Agenda for Health and Wellness* (pp. 13–38). Washington, DC: American Psychological Association.
- Okoro, C. A. (2018). Prevalence of Disabilities and Health Care Access by Disability Status and Type Among Adults—United States, 2016. *Morbidity and Mortality Weekly Report*, 67(32), 882–887.
- Pendo, E., & Iezzoni, L. I. (2019). The Role of Law and Policy in Achieving Healthy People's Disability and Health Goals around Access to Health Care, Activities Promoting Health and Wellness, Independent Living and Participation, and Collecting Data in the United States. Retrieved July 17, 2020, from https://www.healthypeople.gov/sites/default/files/LHP_Disability-Health-Policy_2020.03.12_508_0.pdf
- Pendo, E., Gatter, R. and Mohapatra, S. (2020). Resolving Tensions Between Disability Rights Law and COVID-19 Mask Policies. *Maryland Law Review Online* (forthcoming Summer 2020).
- Rehabilitation Act, 29 U.S.C. §701 et seq. (1973).
- United States Equal Employment Opportunity Commission (2020). What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws. Retrieved July 17, 2020, from <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>
- Yee S., Breslin, M. L., Goode, T. D., Haverkamp, S. M., Horner-Johnson, W., Iezzoni, L. I., & Krahn, G. (2019). Compounded Disparities: Health Equity at the Intersection of Disability, Race, and Ethnicity. Retrieved July 17, 2020, from <https://dredf.org/2018/01/19/compounded-disparities-health-equity-intersection-disability-race-ethnicity/>

Fostering the Civil Rights of Health

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SUMMARY. Pandemics, like climate disasters, thrive on inequality. COVID-19 is no exception, flourishing where inequality has weakened the social fabric. One of these weaknesses is long-standing racial discrimination, which has produced unjust, racialized disparities in COVID-19 transmission and mortality, and disproportionate economic harm to people of color. Efforts to address these racial disparities have been hindered by a series of governance and advocacy disconnects. Some of these disconnects are well-known and widely discussed, such as fractures in federal, state, and local leadership that have politicized basic public health measures such as wearing masks. Less-well understood is the society-wide failure to adequately address racial discrimination in all its forms. This has perpetuated the disconnection of public health and civil rights advocacy from one another, and the disconnection of public health and civil rights professionals from anti-discrimination social movements. One promising tool to bridge these disconnects is research on the social determinants of health. Highlighting the ways in which discrimination is a public health problem allows legal advocates to use civil rights law as a health intervention and public health advocates to squarely challenge discrimination. In keeping with the emergent health justice movement, civil rights and public health advocates can amplify their effectiveness by partnering with organizations that fight discrimination. We call this approach “the civil rights of health.” This agenda for action requires (1) integrating civil rights and public health initiatives and (2) fostering three-way partnerships among civil rights, public health, and justice movement leaders (Harris & Pamukcu, 2019).

Introduction

Although COVID-19 has spared no geography or walk of life—inflicting heads of state as well as low-wage workers around the world—it has taken a disproportionate toll on people of color in the United States. Black Americans have been hardest hit, with a death rate currently at 2.5 times that of their white counterparts (The COVID Tracking Project, 2020).

The reasons for these disparities in COVID-19 transmission and mortality are various, interrelated, and compounding. There are racial disparities in the rates of chronic diseases and conditions that interact harmfully with the virus, such as diabetes, heart disease, and obesity. Due to a legacy of discrimination and disinvestment, people of color are disproportionately likely to live in communities segregated from white populations, and to live in conditions conducive to the spread of infectious disease, such as overcrowded or substandard housing. Under the current system of mass incarceration, U.S. prisons and immigration detention centers are overpopulated by Black and Latino people—inmates, detainees, and staff.

Pre-existing economic disparities also compound the virus’s racial effects. These disparities include a widening racial wealth

gap and employment inequalities, such as the fact that so-called essential workers are more likely to be people of color. So far, the disastrous economic effects of the pandemic are reflecting the racially disparate health outcomes of the virus. For example, more than 40% of Black business owners reported they were not working in April, while only 17% of white business owners said the same (Fairlie, 2020).

The pandemic is disproportionately costly to the longevity, health, and prosperity of people of color. Yet many government entities, particularly at the federal level, have been slow to measure—let alone address—the racialized consequences of COVID-19. The Centers for Disease Control and Prevention (CDC), for example, has not provided complete race and ethnicity information in their released COVID-19 data, even after being sued by the New York Times (Oppel Jr. et al., 2020). Economically, federal stimulus programs appear to have benefited business owners of color less than other business owners (Flitter, 2020). We still need more data, however, to understand the full impact of economic mitigation measures on marginalized communities.

Disconnects in Governance and Advocacy

A series of disconnects in American governance has exacerbated

the problem. Some of these disconnects are longstanding and structural, such as tensions over the boundaries of federal, state, and local government authority. Others involve debates between whether resources constitute public or private goods, like the fractured governance of health insurance and health care between state and market provision. There are even growing rifts between scientific experts and research on the one hand, and political leadership and governance on the other.

Some of these disconnects appear to have been intentionally deepened, particularly at the federal level. For example, the Trump administration has disclaimed responsibility for coordinating provision of personal protective equipment (see Chapter 20 for more discussion), withdrawn support for the World Health Organization (WHO) discussed in Chapter 11, and undermined the credibility of the director of the National Institute of Allergy and Infectious Diseases (NIAID).

A less recognized, conceptual disconnect plays an important role in the disproportionate toll of COVID-19 on people of color. What we know about the structural nature of discrimination does not align with how American legal and policy advocacy has actually responded to discrimination.

Notably, civil rights legal advocacy and public health initiatives have conventionally been disconnected from one another—and each, for different reasons, has failed to fully engage with all forms of racial discrimination. While there has been increasing recognition of the connection between health and discrimination, both civil rights and public health advocates are struggling to close a persistent and, by some measures, widening racial health gap (National Academies for Sciences, Engineering, and Medicine, 2017).

Even when public health research or interventions have aligned with the force of law, there is grave potential to perpetuate or even intensify discrimination. This is a particular risk when public health concerns overlap with widespread social biases like racism and sexism. Historical examples range from eugenics statutes such as Puerto Rico's Law 116 (which institutionalized the population control program that resulted in the mass sterilization of Puerto Rican women) to the punitive legal and policy responses to the racialized panic over "crack babies" (which led to the widespread criminalization of pregnant cocaine users, despite being based on inconclusive research) (McGinnis, 1990).

One promising way to bridge these disconnects is to build a sustained partnership between public health, civil rights legal advocacy, and anti-discrimination social movements—a partnership we call "the civil rights of health." Government can play a key role in facilitating this timely alliance.

Bridging the Disconnects with the Civil Rights of Health

As public health advocates have recognized, the root cause of racialized health disparities is discrimination. Individual discrimination, especially stemming from implicit bias, plays a role in sustaining disparities across complex systems, from health care to the labor market. Less visibly and more insidiously, institutional

and structural discrimination deepens these disparities and sustains them over time.

Failure to reckon with our nation's history of racism has weakened the legal tools available to address discrimination and hindered the progress of public health research and interventions. Public health advocacy has too often focused on universal interventions that improve health overall but leave the racial health gap intact, or has pursued individual behavior change campaigns that address the symptoms of discrimination rather than discrimination itself. Meanwhile, civil rights advocacy has been hampered by legal tools that treat explicit interpersonal prejudice as the root cause of racism, ignoring institutional and structural forms of discrimination. Moreover, public health and civil rights advocates have pursued their work in parallel but rarely aligned their anti-discrimination efforts.

The literature on the social determinants of health offers a way beyond these disconnects. This literature documents and analyzes how interpersonal, institutional, and structural discrimination decreases the length and quality of people's lives across populations and geographies. The COVID-19 crisis offers an opportunity to train the attention of civil rights and public health advocates on the shared goal of fighting discrimination in all its forms in the service of better health for all—an approach we call "the civil rights of health."

A Framework for Action

The civil rights of health framework suggests at least three priorities in this pandemic: (1) collecting effective and actionable data, (2) connecting the dots between health disparities and structural discrimination, and (3) partnering with anti-discrimination community organizations.

First, in order to take effective action, it is necessary to have a body of accurate data on COVID-19 racial disparities. State and local public health authorities should track coronavirus racial impact data alongside other relevant demographic categories. Such robust and disaggregated data would enable officials to properly prioritize their efforts. Many local governments have already begun this work. In California's Bay Area, for instance, local governments and health officials are increasingly targeting medical and financial resources where they are most needed based on demographics and place (Palomino & Sanchez, 2020). In another example, Chicago Mayor Lori Lightfoot announced the creation of a "racial equity rapid response team" to collect and share demographic data, and to work with community organizations to prepare what she called a "hyperlocal" response to racialized disparities in illness and death (Chicago Recovery Task Force, 2020). We additionally recommend data collection efforts be coordinated so that advocates can effectively combine data sources to produce a broader picture of the disparate effects of the virus.

Second, government entities should promote conceptual frameworks that connect health disparities to structural discrimination. In recent weeks, for example, local governments have issued declarations that frame racism as a public health crisis. Although these declarations typically have no legal

enforceability, funding mechanisms, or mandates for action, they help lay the conceptual groundwork for establishing partnerships among previously-siloed entities, priorities, and programs. In Chicago, for example, the city's Recovery Task Force Report links ending racial health disparities with the goal of poverty reduction and the expansion of economic opportunity (Chicago Recovery Task Force, 2020).

Third, anti-discrimination community organizations should be equal partners with legal and public health professionals for the resulting initiatives to be effective and just. As an example, the Movement for Black Lives (M4BL) has organized mass public protests against police brutality against Black and other marginalized people, and called for "defunding the police." This demand, along with widespread community mobilization, has sparked vigorous conversations about the underfunding of key social determinants of health, such as education and safety net programs. This, in turn, paves the way for innovative policy conversations and initiatives against structural racism — such as treating community violence as a public health problem rather than a criminal justice problem. The success of M4BL in changing the public conversation illustrates why the civil rights of health is aligned with the emergent health justice movement.

Like environmental justice, reproductive justice, and other "[x] justice" movements, health justice embraces the leadership of frontline communities in systemic change efforts alongside professionals in law and science. Frontline communities, represented by anti-discrimination social movements, have the capacity to change the political landscape, making public space in which to imagine bold new initiatives and creating the political for implementation. These movements can also challenge abuses of power, including abuses by legal and public health actors. Finally, movement leaders often have the ability to reach marginalized communities and populations who may have good reason to distrust public officials and expert advice.

The civil rights of health is premised on the recognition that ending structural racial discrimination is necessary to ending racial health disparities. Government entities and advocates tasked with the protection of civil rights should draw on the social determinants of health literature to pinpoint the ways that racial discrimination and marginalization across systems create and sustain differential vulnerability to COVID-19. Conversely, public health advocates, many of whom have been slow to address discrimination as a health issue, must wholeheartedly embrace anti-discrimination law and policy as an essential public good necessary for health equity. Both civil rights and public health professionals should accept the expertise and leadership of frontline communities in planning and advocacy rooted in anti-racist values.

As noted previously, an endemic challenge in social change work is the tension between universal policies and policies targeted to benefit marginalized populations. Policies addressing the health and economic harms of COVID-19 can use a "targeted universalism" approach to effectively address the racialized impact of the virus. Targeted universalism recognizes that policies directed toward supporting stigmatized populations are politically vulnerable

for that very reason. It is therefore advisable to look for ways to combine universal objectives and programs with targeted corrective justice projects. The targeted universalism framework breaks the approach down to five steps:

1. Set a universal goal.
2. Assess the general population performance relative to the universal goal.
3. Assess and identify the performance of groups that are performing differently with respect to the universal goal.
4. Assess and understand the structures and other factors that support or interfere each group from achieving the universal goal.
5. Develop and implement targeted strategies for each group to reach the goal (Powell et al., 2019).

Targeted universalism does not preclude the possibility of backlash — as officials in Harris County, TX discovered, for example, when they decided to focus flood control efforts on the least resilient communities rather than prioritizing the communities with the highest property values. But the targeted universalism framework, especially in the context of a global health pandemic, helps make visible the links between the corrective justice goal of anti-discrimination and the universal goal of better health for all. 🌞

Recommendations for Action

Federal government:

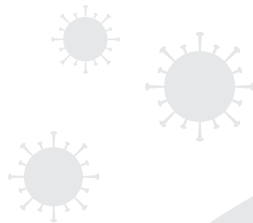
- Should improve data collection efforts across agencies to ensure critical demographic data about health outcomes and the broader impacts of the pandemic (including results of mitigation efforts) is collected and analyzed, while privacy is protected.
- Agencies, including the CDC, should coordinate and standardize data collection efforts so that data sets can be effectively combined, and ensure that complete data is made publicly available.
- Congress should dedicate and increase resources to federal agencies to coordinate with civil rights and public health organizations to inform, enforce, and further civil rights protections.
- Agencies should develop guidance for the use of “targeted universalism” as a policy and planning frame in order to benefit all populations while specifically addressing the harms of racism.

State governments:

- Should improve data collection efforts across agencies and departments to ensure critical demographic data is collected and analyzed to properly inform policy decisions.
- Should work in tandem with local governments to identify and address racial health disparities and support the distribution of resources to eliminate them.
- Should devote resources to supporting community-based organizations working to address the social determinants of health, the racial health gap, and/or anti-discrimination efforts.
- Should realign government budgets around preventive health and provide community budgeting participation and oversight.
- Should work with agencies and departments to develop guidance on the use “targeted universalism” as a policy and planning frame, in order to benefit all populations while specifically addressing the harms of racism.

Local governments:

- Should collect detailed data on the populations and geographies most affected by COVID-19 and use this data to effectively allocate resources to the most impacted people and places; where possible, pursue coordinated regional data collection efforts.
- Should recognize and address racism as an institutional and systemic issue, such as the proliferation of local government declarations characterizing racism as a public health crisis.
- Should use “targeted universalism” as a policy and planning frame in order to benefit all populations while specifically addressing the harms of racism.
- Should foster three-way partnership among civil rights, public health, and anti-discrimination movement leaders.
- Should pursue “hyperlocal” rapid responses in partnership with community organizations.
- Should realign government budgets around preventive health and provide community budgeting participation and oversight.



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References

- Chicago Recovery Task Force. (2020). Forward Together: Building a Stronger Chicago. Retrieved July 23, 2020, from <https://www.chicago.gov/content/dam/city/sites/covid/task-force/Chicago%20Recovery%20Task%20Force%20-%20Advisory%20Report.pdf>
- Fairlie, R. W. (2020). The Impact of COVID-19 on Small Business Owners: Evidence of Early-Stage Losses from the April 2020 Current Population Survey. Retrieved July 23, 2020, from <https://www.nber.org/papers/w27309.pdf>
- Flitter, E. (2020). Few Minority-Owned Businesses Got Relief Loans They Asked For. Retrieved July 23, 2020, from <https://www.nytimes.com/2020/05/18/business/minority-businesses-coronavirus-loans.html>
- Harris, A. P., & Pamukcu, A. (2019). The Civil Rights of Health: A New Approach to Challenging Structural Inequality. *UCLA Law Review* (forthcoming 2020-2021).
- McGinnis, D. M. (1990). Prosecution of Mothers of Drug-Exposed Babies: Constitutional and Criminal Theory. *University of Pennsylvania Law Review*, 139(2), 505-539.
- National Academies for Sciences, Engineering, and Medicine (2017). The State of Health Disparities in the United States. In J. N. Weinstein, A. Geller, Y. Negussie, & A. Baciu (Eds.), *Communities in Action: Pathways to Health Equity* (pp. 57-98). Washington (DC): National Academies Press.
- Oppel Jr., R. A., Gebeloff, R., Lai, K. K. R., Wright, W., & Smith, M. (2020). The Fullest Look Yet at the Racial Inequality of Coronavirus. *New York Times*. Retrieved July 23, 2020, from <https://www.nytimes.com/interactive/2020/07/05/us/coronavirus-latino-african-americans-cdc-data.html>
- Palomino, J., & Sanchez, T. (2020). Latinos' Coronavirus Burden. Retrieved July 23, 2020, from <https://www.sfchronicle.com/bayarea/article/Bay-Area-Latinos-hit-hardest-by-coronavirus-15252632.php>
- Powell, J. A., Menendian, S., & Ake, W. (2019). Targeted Universalism: Policy & Practice. Retrieved July 29, 2020, from https://haasinstitute.berkeley.edu/sites/default/files/targeted_universalism_primer.pdf
- The COVID Tracking Project. (2020). The COVID Racial Data Tracker. Retrieved July 23, 2020, from <https://covidtracking.com/race>