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Assessing Laws and Legal Authorities for Public Health Emergency Legal Preparedness

Brian Kamoie, Robert M. Pestronk, Peter Baldrige, David Fidler, Leah Devlin, George A. Mensah, and Michael Doney

Introduction

Public health legal preparedness begins with effective legal authorities, and law provides a key foundation for public health practice in the United States. Laws not only create public health agencies and fund them, but also authorize and impose duties upon government to protect the public's health while preserving individual liberties.¹ As a result, law is an essential tool in public health practice² and is one element of public health infrastructure, as it defines the systems and relationships within which public health practitioners operate.³

For purposes of this paper, law can be defined as a rule of conduct derived from federal or state constitutions, statutes, local laws, judicial opinions, administrative rules and regulations, international codes, or other pronouncements by entities authorized to prescribe conduct in a legally binding manner. Public health legal preparedness, a subset of public health preparedness,⁴ is defined as attainment of legal benchmarks within a public health system.⁵ Law is one of four core elements of public health legal preparedness (the remaining three – competencies, information, and coordination – are each the subject of individual papers that follow).

In this paper we briefly describe the evolution and status of essential legal authorities for public health preparedness. Our review focused on *three* specific preparedness initiatives – health care system surge capacity, the Pandemic and All-Hazards Preparedness Act, and implementation of the International Health Regulations. These issues do not represent the entire range of legal preparedness nor the only relevant perspectives. The limited scope of this paper prevents a comprehensive treatment of these and other issues we considered. Rather, we chose these three initiatives because they exemplify the span of public health legal preparedness from the state and local, federal, and international perspectives.

After a brief overview of these initiatives, we describe several themes that emerged during our review. First, the series of events from September 11, 2001 and the anthrax attacks later that year to Hurricane Katrina in 2005 prompted a flurry of legislative and regulatory activities that sought to provide new authorities⁶ at every level, modernize public health law,⁷ and reorganize Federal preparedness and response functions.⁸ Collectively, these legal reforms sought to improve the legal frameworks for the attainment of public health preparedness. Reviewing this legal landscape raises

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the questions of whether new laws and legal authorities are still needed, as well as whether the public health community is making the most effective use of existing authorities.

An additional question is whether existing laws form a barrier to achieving effective preparedness and response to public health emergencies. How we improve health care system surge capacity while complying with a patchwork of existing laws is a challenge at the state and local levels. Finally, the paper serves as a foundation for the companion paper that addresses gaps and potential limitations in existing authorities that merit consideration for action.

Background

The 20th century witnessed significant public health achievements, from advancements in the control of infectious diseases and motor vehicle safety to vaccination and worker safety.⁹ Additionally, the prevention and control of non-communicable chronic diseases, such as heart disease and stroke and their associated risk factors, represent one of the greatest public health achievements of the past century.¹⁰ Law played a key supportive role in these achievements.¹¹ Among the essential legal authorities that enable such achievements are laws that establish public health and related agencies, confer authorities upon those agencies to act (e.g., public health surveillance and investigation, environmental regulation, and public health interventions), and provide funding to those agencies.

Most notable, for purposes of this paper, may be the evolution of laws that relate to emergency preparedness and response, and the subset of those laws that address the preparedness of the public health system to respond to emergencies and disasters.

At the state level, the primary legal authority to respond to emergencies has been the police power, or the authority of the state to enact laws and regulations that protect the health, safety, and welfare of citizens.¹² The police power is among the powers reserved to the states under the Tenth Amendment to the U.S. Constitution.¹³ The type of laws and regulations enacted under this authority that have a direct impact on public health include disease reporting and medical surveillance, personal control measures (e.g., mandatory vaccination), traffic safety, and nuisance abatement.

At the federal level, the Constitution empowers the federal government to regulate matters that affect public health through the Commerce Clause,¹⁴ which authorizes regulation of interstate and foreign commerce, and Congressional authority to tax, spend, and address national security and foreign affairs.¹⁵ Based on these broad foundational authorities, federal law regarding the response to emergencies and disasters

has evolved over time to reflect an emphasis on an all-hazards approach that enables preparedness and response to emergencies and disasters, both natural and manmade, including terrorism.

The primary framework for federal emergency response authority is the Robert T. Stafford Disaster Relief and Emergency Assistance Act,¹⁶ which outlines the programs and processes through which the federal government provides disaster and emergency assistance to state and local governments, tribes, eligible private nonprofit organizations, and individuals affected by a major disaster or emergency as declared by the President. The primary federal public health response authority is the Public Health Service Act,¹⁷ which authorizes the Secretary of the Department of Health and Human Services to, among other actions, declare a public health emergency in response to the introduction and spread of communicable diseases, bioterrorism, or other situation that threatens the public's health.

The evolution of these legal frameworks over the 20th century and the development of comprehensive emergency management systems such as the National Incident Management System (NIMS) and the National Response Plan (NRP) have deviated from traditional civil defense and hazard-specific legislation and systems to focus on an all-hazards approach organized under the general framework of homeland security. This general homeland security framework includes the statutes, regulations, and the Presidential directives that, among other actions, created the Department of Homeland Security and the White House Homeland Security Council and required a wide range of preparedness and response planning. Recent legislation¹⁸ requires the development of a National Health Security Strategy to address the preparedness of the nation to respond to public health emergencies, which is a similar framework to U.S. government national security¹⁹ and homeland security²⁰ strategies.

Coupled with this new all-hazards approach and focus is the evolution of safeguards to protect individual liberties against unconstitutional government action. These safeguards include due process protections against deprivation of individual liberty (e.g., interstate travel restrictions and compulsory vaccination) and procedural protections that require proper notice and hearings before government can act. Protection of individually identifiable health information to ensure privacy is another example of enhanced individual protections, although there are limitations on these protections during emergencies.²¹ As careful observers have noted, development of individual safeguards over the 20th century has occurred at the same time that public health officials have been able

to move away from community-wide disease control measures such as quarantine due to medical advances (e.g., vaccines and pharmaceuticals).²² Although not yet tested in case law, the developments in constitutional due process may be relevant to the exercise of police powers to respond to public health emergencies. The threat of an influenza pandemic from the H5N1 strain of avian influenza has renewed attention on balancing the potential need for community-wide measures and the concomitant need to protect individual liberties.

Essential Legal Authorities and Selected Issues

With this broad framework, we turn to three specific issues that highlight the development of public health legal preparedness at the state/local, federal, and international levels. We examine several specific legal authorities and raise broader questions of the effectiveness of the current legal landscape and potential gaps to address.

1) Surge Capacity

With the seminal events of 2001 to 2005, a great deal of attention has focused on “filling gaps” in the legal authority of states and the federal government to respond to emergencies affecting public health. The urgency to complete this process was heightened by the potential threat of pandemic influenza. Because of the potential for rapid spread of pandemic flu and the potential absence of effective countermeasures in the initial months, there has also been much focus on how to address the anticipated overwhelming “surge” of patients into the health care system, some possibly requiring significant respiratory support. Such a surge could occur statewide or nationwide and continue in waves over months. Traditional means of dealing with sudden but localized surges of patients from an event such as a mass transportation accident may likely be ineffective. For example, communities may not have additional health care facilities immediately available to which surplus patients could be redirected by health facilities legally incapable of accepting more patients. Even the most promising new concepts in building surge capacity, such as “ER One” (an emergency department renovation plan that allows a standard 60-70 bed emergency department to accommodate four times that number of patients with less than 30 minutes’ notice and increase its normal patient volume tenfold with only a few hours’ notice),²³ may not meet bed requirements in the setting of pandemic flu.

In an emergency, the primary responsibility for the preservation of life and property falls on government,

particularly at the state and local levels. The California Government Code, for example, specifically enunciates the state’s responsibility to mitigate the effects of natural, man-made and war-caused emergencies.²⁴ Thus, it would be the responsibility of the state to address, to the extent possible, the surge of patients that the health care system cannot handle. If a state response became overwhelmed, federal resources would likely augment state capabilities. These facts mean it is in the interest of government (both state and local) to maximize the number of patients that can be absorbed by the health care system.

At the same time, however, the health care industry is highly regulated, and the standards established by regulation often restrict the ability of the health care system to absorb and treat additional patients. These standards range from facility licensing and certification requirements to labor and employment laws, from professional licensing requirements to standards for reimbursement.²⁵ These laws were not written with an eye toward their operation in a public health emergency. The potential liabilities to the health care community for deviating from the regulatory standards, however, can be criminal, administrative and civil, and can include fines and loss of certification, among other penalties.

While it may be possible for regulatory agencies to waive the enforcement of some or all standards during an emergency, doing so has its own risks as those standards may continue to provide the guidance the health care provider needs to meet for purposes of avoiding liability. A violation of applicable standards that allegedly results in an unfavorable medical outcome can become the basis for a claim of negligence on the part of the provider. Thus, the greatest obstacle to the regulated health care system’s expanded participation in emergency relief may be the state’s own standards. Absent a modification, suspension or waiver of the standards, there may be little legal or economic incentive for health care providers to risk providing the additional services that the state may need.

Some states authorize the suspension of regulatory statutes and regulations where strict compliance would impair the mitigation of the effects of an emergency.²⁶ In California, the process of modifying, suspending or waiving specific standards requires the identification of (1) the authority to suspend regulatory requirement, (2) which standards impair the expanded utilization of the healthcare system, (3) a mechanism to inform those with the political authority to implement a suspension, (4) a mechanism to determine what circumstances will justify the suspension, (5) a system of monitoring adverse effects or events for purposes

of evaluation, and (6) a mechanism for determining when the standards should be reinstated.²⁷

Thus, among the primary themes of our review is whether the operation of existing laws impairs public health legal preparedness to respond to a disaster or emergency.

2) *The Pandemic and All-Hazards Preparedness Act*

The President signed the Pandemic and All-Hazards Preparedness Act (PAHPA)²⁸ into law in December 2006. The statute builds upon the homeland security framework described earlier and represents the most comprehensive legislative treatment of public health preparedness to date. The 137-page statute affects all aspects of federal public health preparedness and response functions, consistent with existing federal policies outlined in relevant Homeland Security Presidential Directives and the National Response Plan.

Among other things, PAHPA directed the transfer or alignment of a variety of preparedness and response programs within the U.S. Department of Health and Human Services by a new Assistant Secretary for Preparedness and Response who is appointed by the President and confirmed by the Senate. The law provides new authorities in the development and acquisition of medical countermeasures, international preparedness and response programs, renews emphasis on the alignment of preparedness and response at all levels of government, and requires evidence-based benchmarks and standards that measure levels of preparedness. The statute also requires the development of a National Health Security Strategy, to include an evaluation of the preparedness of federal, state, local, and tribal entities based on the required evidence-based benchmarks and objective performance standards. The initial strategy is due in 2009 and then every four years thereafter.

At the federal level, in addition to creating new authorities, PAHPA renews a general movement toward alignment of existing preparedness and response activities both within HHS and across the federal government. This raises the second theme whether – given the substantial body of legal authorities that now exist – relevant partners are implementing those authorities in a way that maximizes their effectiveness.

3) *International Health Regulations*

Public health legal preparedness also occurs on the global stage. The goal of the newly revised International Health Regulations (IHR)²⁹ is to protect the health of people worldwide without interfering with travel and trade. The regulations took effect in June 2007 and represent a legally binding agreement regarding

“public health emergencies of international concern.”³⁰ Such events are defined as extraordinary public health events that pose a health risk – through the international spread of disease – to the rest of the world.

Consistent with the domestic evolution of public health legal preparedness from disease or incident-specific laws, the 2005 revision of the 1969 version of the IHR broadens the scope of coverage from cases of cholera, plague and yellow fever to all events that may constitute public health emergencies of international concern and requires the reporting of other serious international health risks, irrespective of origin or source. The new IHR require notification of the World Health Organization and outline new routine public health measures for the entry of people and goods into a country.

Discussion and Summary

The three specific areas examined in this paper address public health legal preparedness at the state and local, federal, and international levels. In this broadest span and range of issues, two key themes emerge. First, are we using existing laws effectively? Have we adequately trained public health professionals and others engaged in public health preparedness in this legal landscape? Do we need additional authorities to fill gaps in public health legal preparedness?

Second, as noted by the analysis of health care system surge capacity, have we unintentionally impeded public health preparedness, and its subset of legal preparedness, with existing laws? For example, are the legal requirements related to the operation of health care systems (which have very legitimate bases in protecting patient and worker safety) an impediment to meeting surge capacity during a public health emergency? If so, how might we best balance the day-to-day operational requirements with preparedness to respond during a public health emergency for which waiver of certain requirements might best accomplish public health preparedness? Have we adequately (1) identified the laws authorizing waivers or suspensions; (2) identified the laws or regulations that may need to be waived or suspended; and (3) drafted the appropriate executive orders to accomplish waiver or suspension?

Public health legal preparedness begins with effective legal authorities. We have considered the existing legal landscape, whether relief from existing law might be needed, and whether we have made maximum use of the authorities we have. While the answers are not immediately clear and require additional analysis, one thing is certain. Given the complexity of public health preparedness, law will remain an essential tool in public health practice.

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