

ANNEX 3: SPECIFIC GUIDANCE ON LEGAL ISSUES RELEVANT TO ALLOCATION OF SCARCE MEDICAL RESOURCES AND SERVICES DURING PUBLIC HEALTH EMERGENCIES

The Ethical Guidelines on Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan must be applied in accordance with federal, state, and local law. Such governing law draws on Constitutional provisions, statutes, regulations, and court decisions. This attachment addresses four key legal issues relevant to the allocation of scarce medical resources during public health emergencies: 1) the authority of the government to declare emergencies and/or disasters; 2) licensing of health care professionals and institutions; 3) applicable standards of care; and 4) liability of health care professionals and volunteers operating under emergencies.

The Committee provides this attachment only as a guide. Health care professionals and institutions should consult with their respective legal counsel on specific questions, situations, and concerns they may encounter during a public health emergency.

1. The ability to declare an emergency or disaster and the consequences of such a declaration.

A number of different legal provisions grant government officials at the federal and state levels the ability to declare an emergency, disaster, or public health emergency. Typically, state-level decisions drive emergency response activities, since many of these activities are governed by laws grounded in the state's police power. In Michigan, the Public Health Code¹ and the Emergency Management Act² address the management of emergencies and disasters. Both of these laws are construed broadly to allow state officials sufficient power to respond effectively to serious threats to the public's health and affect the ability to make allocation decisions about scarce resources during public health emergencies.

a. Michigan Emergency Management Act

The Emergency Management Act establishes the powers of the Governor to declare an emergency or disaster and to undertake the necessary actions to deal with the emergency or disaster.³ The Governor, after a declaring a state of emergency or disaster for the entire state or a region of the state, may take any necessary and appropriate action under the circumstances, including suspension of regulatory statutes, orders, or rules related to the conduct of state business; seizure of property (with compensation); control of access to and from affected areas; as well as a selection of other specified powers.⁴ This Act also permits county and municipal governments to declare a local state of

¹ Michigan Compiled Laws (MCL) §333.1101 et seq.

² Michigan Compiled Laws (MCL) §30.401, et seq.

³ Michigan Compiled Laws (MCL) §30.403.

⁴ Michigan Compiled Laws (MCL) §30.405.

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emergency.⁵ These powers could be used to control access to scarce medications in the possession of state or local agencies, or could be used to suspend normal regulations related to provision of medical resources.

b. Michigan Public Health Code

The Public Health Code grants the Michigan Department of Community Health (MDCH) and local health departments a wide range of public health powers that may be exercised in responding to a declared emergency or disaster, including powers to isolate and quarantine infected or exposed persons; to restrict movement and interaction of people through closure of roads, public venues, and schools, and suspension of public gatherings; and to coordinate medical interventions such as disease screening and mass vaccination efforts. The Public Health Code authorizes the issuance of emergency orders that can directly impact medical resource allocation.⁶ For example, the Director of MDCH issued an order limiting access to influenza vaccines to persons in high risk categories (including young children, pregnant women, adults over 65, people with underlying chronic medical conditions, and health care workers involved in direct patient care) during an influenza vaccine shortage in 2004. Health providers who violated this order during the two months it was in effect could have faced fines or sanctions imposed by the state.⁷

c. Stafford Act

At the federal level, several laws permit emergency or disaster declarations and authorize response efforts. The Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1974⁸ allows the President to declare an emergency or major disaster. A presidential declaration of emergency or major disaster under the Stafford Act usually occurs at the request of a state governor. A declaration allows for the federal government to provide assistance to state and local response efforts and to coordinate these response efforts if necessary. Under a Stafford Act emergency declaration, the response activities of all federal agencies are under the authority of the Federal Emergency Management Agency (FEMA) of the Department of Homeland Security (DHS). While the Stafford Act does not directly address issues of scarce resource allocation, the federal resources available through the Act and the federal coordination authorized by the Act may impact the availability of federally-controlled medical resources and personnel to members of the affected populations.

⁵ Michigan Compiled Laws (MCL) § 30.410.

⁶ Michigan Compiled Laws (MCL) §333.2251.

⁷ Michigan Compiled Laws (MCL) §333.2261.

⁸ Public Law 93-288 and as codified as amended at 42 U.S.C. §§ 5121-5206 (2007).

d. Public Health Service Act

Pursuant to the Public Health Service Act (PHSA),⁹ the Secretary of the Department of Health and Human Services (HHS) coordinates health and medical services during declared federal emergencies or major disasters. Additionally, the PHSA authorizes the HHS Secretary to declare a public health emergency, which permits the Secretary to take appropriate actions to respond through the provision of economic and logistical support, coordination, and expertise. By exercising these powers, HHS is able to expedite the availability of resources to alleviate a shortage. The PHSA gives HHS authority to coordinate activities related to vaccine development, stockpiling of medical resources, and immunization programs, as well as research and investigation into the cause, treatment, and prevention of the public health emergency. The PHSA allows the Secretary to initiate the process to use unapproved products or approved products for unapproved uses or to waive certain regulatory requirements.¹⁰ The Public Health Security and Bioterrorism Preparedness and Response Act of 2002¹¹ amended the PHSA to establish the National Response Framework and the Strategic National Stockpile, as well as providing the HHS with the authority to suspend certain HIPAA (Health Insurance Portability and Accountability Act) and EMTALA (Emergency Medical Treatment and Labor Act) regulations during a public health emergency. On the national level, such powers authorize the HHS to effectively coordinate the appropriate federal resources to optimize response to the public health emergency when state and local resources may be diminished.

Formal declarations of a state of emergency, disaster, or public health emergency streamline access to potentially useful resources and may impact the required standards of care applicable to the response efforts (see section 3 below). Federal and state public health and emergency laws link a declaration of emergency to the provision of funds or specific aid to the area affected by the emergency, and in some instances provide the authority for directly imposing requirements on resource allocation decisions. Furthermore, these declarations may alter the legal environment in relevant ways that affect licensure and liability as described in the sections that follow.

2. Licensing of Personnel and Institutions in Emergency Situations, or Instances of Shortage.

Health care professionals must be licensed in the state of Michigan in their respective roles as physician, nurse, pharmacist, social worker, etc. to provide services. Such licensing requirements serve to protect the public from fraudulent practice as well as distinguish roles and competencies among health professionals. During a public health emergency, scarcity may require efforts to expand staff capacity to deliver the necessary services across health care and public health systems.

⁹ Public Health Service Act, 42 U.S.C. 201 et. seq. (2007) as amended.

¹⁰ 42 U.S.C. 247d

¹¹ Public Law 107-188, 42 U.S.C. 201, The Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

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Several state laws in Michigan relax the normal professional license requirements under certain circumstances during a public health emergency. As a means of coping with medical professional shortages during a time of crisis these laws may allow licensed out-of-state health professionals to practice without specific Michigan licensure or other persons with professional training to perform certain professional tasks without meeting the usual licensure requirements.

- A Michigan license is not required for an individual who by education, training, or experience substantially meets the state’s licensing requirements while rendering medical care in a time of disaster or while rendering medical care to an ill or injured individual at the scene of an emergency.¹²
- A Michigan license is not required for an individual deployed under the Emergency Management Assistance Compact who is licensed in another state party to the compact.¹³
- During a declared emergency or disaster, the Governor may suspend regulatory laws that impede the response to the emergency in an effort to expedite care, including licensure requirements.¹⁴
- The Michigan Emergency Management Act provides that if an emergency or disaster has been declared, health professionals have an expanded scope of practice provided that they practice “under the supervision of a member of the medical staff of a licensed hospital.”¹⁵
- The Governor has the power to waive licensing requirements in the event that a health professional needs to provide services outside the normal scope of the license or a health care facility needs to expand space in excess of its existing license.¹⁶
- The Public Health Service Act permits the waiver of some health professional and health facility requirements set by Medicare and Medicaid. The Department of Health and Human Services can issue a waiver under section 1135 of the Social Security Act to waive requirements that health care professionals be licensed in state where they are providing services if they have an equivalent license in another state (this only applies for purposes of Medicare, Medicaid, and CHIP reimbursement). Section 1135 waivers can also be issued to eliminate EMTALA sanctions for transferring patients to alternative locations for medical screening.

These various provisions allow for the relaxation of licensing requirements for health professionals and health facilities during public health emergencies. Expansion of the availability of medical resources and services can be advanced by the use of these provisions, thereby reducing scarcity.

¹² Michigan Compiled Laws (MCL) § 333.16171.

¹³ Michigan Compiled Laws (MCL) § 3.991.

¹⁴ Michigan Compiled Laws (MCL) § 30.405.

¹⁵ Michigan Compiled Laws (MCL) § 30.411.

¹⁶ Michigan Compiled Laws (MCL) § 30.405.

3. The Government and Altered Standards Of Care During A Public Health Emergency.

Professional standards of care are parameters established by law that outline the duty owed by a health professional to a patient. Professionals who violate the standard of care may be found liable for malpractice under state tort law. In the state of Michigan, all health professionals are expected to comport with the recognized standard of professional skill or care for those in their profession in the same or similar community in which they practice under the circumstances. If the professional is a specialist, he or she must uphold the recognized standard of practice within that specialty given the available facilities under the circumstances.¹⁷ Since circumstances under situations of scarcity during public health emergencies differ from normal practice circumstances, what is expected of professionals under situations of scarcity will also differ. Regardless, the standard of care—acting consistently with the recognized professional skill or care under the circumstances—remains the same.

Since the level of care required to comply with the standard of care varies and changes according to relevant circumstances at the time and place of the act or omission in question, and it can be affected by resource availability. For example, during a public health emergency the standard of care may change because circumstances of scarcity may constrain the options available to a health professional as resources are allocated according to emergency protocols and the Ethical Guidelines. Formally recognized emergency protocols and guidance, while not legally determinative, may provide persuasive evidence for the applicable standard of care during a public health emergency featuring scarcity.

In addition, state and federal law authorizes the government to change the scope of the standard of care during a declared emergency or disaster. A public health emergency declared by the Governor of Michigan allows for the establishment of emergency centers and protocols, including altered levels of care if appropriate, under the Emergency Management Act,¹⁸ or to issues orders for the protection of public health that have the effect of altering the scope of the standard of care.¹⁹ The MDCH order limiting access to influenza vaccines to persons in high risk categories in 2004 (described above) provides another example of this power in action.

Federal law provides for exceptions to EMTALA during public health emergencies, which effectively changes the standard of care for many hospital emergency departments. EMTALA requires that all Medicare-participating hospitals with emergency departments provide certain basic medical screening, treatment, and stabilization for all patients arriving at the emergency department, regardless of ability to pay.²⁰ Hospitals who fail to comply with these requirements can face fines or civil liability. However, HHS may waive EMTALA requirements during public health emergencies if there has

¹⁷ Michigan Compiled Laws (MCL) § 600.2912a.

¹⁸ Michigan Compiled Laws (MCL) § 30.402, et seq.

¹⁹ Michigan Compiled Laws (MCL) §333.2251.

²⁰ 42 U.S.C. § 1395dd et seq.

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been a Presidential declaration of emergency or major disaster under the Stafford Act, a declared public health emergency by the Secretary of HHS, and other procedural steps are followed.²¹ Hospitals who qualify for the EMTALA waiver may direct or relocate patients to off-site locations or transfer patients who have not been stabilized.²² Federal law is essentially recognizing that during public health emergencies, hospital emergency rooms may have difficulty in serving everyone. Taken together, these federal and state provisions greatly impact the expectation on health professionals as they make decisions related to the allocation of scarce medical resources during public health emergencies.

4. Available Liability Protection For Staff and Volunteers During A Public Health Emergency.

Tort liability can be a great concern of individuals and institutions responding during public health emergencies. A number of different legal provisions in state and federal law provide protection from liability for health professionals and volunteers during public health emergencies. The reason for these protections is to incentivize volunteers to participate during public health emergencies. Volunteers can help satisfy needs and fill shortages within the health system during conditions of scarcity. Without protection from liability volunteers may choose not participate.

a. Liability Protection Under Michigan Law.

Michigan law provides liability protection for individuals, institutions, and organizations providing services during a public health emergency if certain conditions are met. These state liability protections, however, do not protect in most cases against liability arising from acts of wanton or willful misconduct or gross negligence.

- Michigan law provides immunity from liability if a healthcare professional (defined to include physicians, physician assistants, nurses, dentists, interns and residents as well as selective allied health professionals) responds to a life-threatening emergency within a licensed medical facility when such a response is not part of his or her professional duties.²³
- Similarly, the Michigan Good Samaritan Act²⁴ extends liability protection to physicians, physician assistants, and nurses (both RNs and LPNs) who provide emergency care at an emergency scene, is uncompensated, and outside the hospital setting. The providers must have acted in good faith and have had no pre-existing patient relationship for the immunity to apply. If the Governor has declared an emergency or disaster, the director of the department of state police may issue a directive relieving persons or groups providing voluntary or private assistance from liability other than for gross negligence.²⁵

²¹ 42 U.S.C. § 1320b-5.

²² See HHS, *CMS Memo: Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Options for Hospitals in a Disaster*, Ref: S&C-09-52 (August 14, 2009).

²³ See Michigan Compiled Laws (MCL) 691.1502

²⁴ Michigan Compiled Laws (MCL) § 691.1501

²⁵ Michigan Compiled Laws (MCL) § 30.407(6)

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- The Michigan Emergency Management Act also establishes liability protection for “state and nongovernmental disaster relief force workers or private or volunteer personnel engaged in disaster relief activity.”²⁶
- The Michigan Public Health Code carries many of the protections against liability for personnel dealing with emergencies within the state. While it does not provide protection against gross negligence, willful or wanton misconduct, or acts or omissions intended to injure the patient, the Code does provide liability protection for individuals serving in specified capacities. There are protections in place for first responders and EMS personnel²⁷, MDCH representatives or health department employees²⁸, those persons participating in mass immunization efforts²⁹, and volunteer health professionals serving the uninsured if certain conditions are satisfied.³⁰
- The Emergency Management Assistance Compact (EMAC) provides the immunity from liability for good faith acts or omissions of officers or employees of the state party rendering aid. Therefore, responders sent to Michigan from other states pursuant to EMAC can claim immunity from liability from any acts or omissions that are not considered willful misconduct, gross negligence, or recklessness.³¹

b. Federal Liability Protection.

The federal Volunteer Protection Act³² (VPA) provides liability protection for the acts or omissions of volunteers working with non-profit and governmental agencies, provided that these volunteers are acting within the scope of their responsibilities, in compliance with state laws regarding the practice of such responsibilities, and not receiving compensation for their efforts other than reasonable reimbursement for incurred expenses. The VPA does not provide liability protection against willful, gross negligence, reckless or criminal misconduct. Taken together, the VPA, the Michigan Good Samaritan Act, and Michigan’s Public Health Code, supply a great deal of liability protection for those who volunteer to respond to public health emergencies within Michigan.

Additionally, individuals and entities engaged in designing, manufacturing, labeling, distributing, selling, donating, administering, etc. pharmaceutical countermeasures during a public health emergency may find protection under the Public Readiness and Emergency Preparedness Act (PREP Act), which modified the PHSA.³³

²⁶ Michigan Compiled Laws (MCL) § 30.411

²⁷ Michigan Compiled Laws (MCL) § 333.20965

²⁸ Michigan Compiled Laws (MCL) § 333.2228; MCL 333.2465

²⁹ Michigan Compiled Laws (MCL) § 333.9203

³⁰ Michigan Compiled Laws (MCL) § 333.16277

³¹ Michigan Compiled Laws (MCL) § 3.991.

³² 42 U.S.C. § 14501 et seq.

³³ Part of the Public Health Service Act, 42 U.S.C. §247d-6d.

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The PREP Act allocates resources, encourages development of response plans by state and local agencies,³⁴ allows for strategic stockpiles,³⁵ and includes provisions for the development of public health countermeasures.³⁶ Because the law encourages rapid development of countermeasures, specifically vaccines and other response drugs, the law protects from liability those persons and organizations who develop, manufacture, distribute, sell, or otherwise have involvement with these products.³⁷ This liability protection, while extremely broad, is intended to provide an incentive for expedited development of these necessary countermeasures without the usual FDA procedural and quality control safeguards, which may be waived in times of emergency.³⁸ Without these protective provisions a company which produces a vaccine which may not be effective, or has unforeseen side effects could be held liable for all harm caused by the drug despite its being used in an unintended way, or before testing could be completed. The PREP component also preempts state law, meaning that no state can afford less protection to these entities protected by a PREP act declaration. The act does not, however, protect companies or other entities from liability for “willful misconduct” as outlined in 42 U.S.C. § 247d-6d, which primarily focuses on intended harm. The Secretary of HHS must designate a specific countermeasure before these strong liability protections apply.³⁹ Currently there are very few such countermeasures recognized.⁴⁰ In summary, the PREP act provides protection for virtually everyone involved in the provision of medical and public health countermeasures. This very broad protection incentivizes the production of new countermeasure, which may reduce scarcity of medical resources during public health emergencies.

³⁴ 42 U.S.C. §247d-3a

³⁵ 42 U.S.C. §247d-6b

³⁶ 42 U.S.C. §247d-6a

³⁷ 42 U.S.C. § 247d-6d

³⁸ 42 U.S.C. §247d-6b

³⁹ 42 U.S.C. § 247d-6d

⁴⁰ The HHS PREP Act website details PREP Act declarations. See <http://www.hhs.gov/disasters/discussion/planners/prepact/index.html>