

Appendix P – Other Legal and Regulatory Issues

The *National Strategy for Pandemic Influenza: Implementation Plan* discusses the waiver and modification of certain legal requirements during pandemic influenza. It asserts, “Depending on the severity of a pandemic, certain requirements may be waived or revised to facilitate efficient delivery of health care services.”

For example, the plan acknowledges that certain Emergency Medical Treatment and Active Labor Act (EMTALA), Medicare, Medicaid, State Children’s Health Insurance Program (SCHIP), and Health Insurance Portability and Accountability Act (HIPAA) requirements may be waived following a declaration of a public health emergency by the Secretary of HHS and a Presidential declaration of a major disaster or emergency.

Some of the Federal, State and local laws and regulations that govern the delivery of health and medical care under normal conditions may need to be modified. These include laws to ensure access to emergency medical care; protect patient privacy and confidentiality of medical information; shield medical providers and other rescuers from lawsuits; govern the development and use of health and medical facilities; and regulate the number of hours health and medical providers can work as well as the conditions in which they work. Relevant laws include but are not limited to the following:

- Emergency Medical Treatment and Active Labor Act (EMTALA)
- Health Insurance Portability and Accountability Act (HIPAA)
- Federal Volunteer Protection Act
- Good Samaritan Law.

Additional types of laws and regulations that relate to the delivery of health and medical care include:

- Occupational Safety and Health Administration and other workplace regulations
- Building codes and other facility standards
- Publicly funded health insurance laws (including Medicare, Medicaid, and the State Children’s Health Insurance Program)
- Laws pertaining to human subject research
- Laws and regulations governing the use and licensure of drugs and devices.

In developing a comprehensive plan for the delivery of health and medical care during pandemic influenza, it is also important to consider mechanisms to allow for legal, regulatory, or accreditation adjustments in the following areas:

- **Liability of providers and institutions for care provided under stress with less than a full complement of resources.** The plan may have to provide for hold harmless agreements or grant immunity from civil or criminal liability under certain conditions.
- **Certification and licensing.** Although it is important to ensure that providers are qualified, it is also important to have flexibility in granting temporary certification

or licenses for EMS personnel and others who are inactive, retired or certified or licensed in other States.

- **Scope of practice.** It may be necessary to grant permission to certain professionals on a temporary and emergency basis to function outside their legal scope of practice or above their level of training. The National EMS Scope of Practice Model and EMS stakeholders, however, stress the need for appropriate education, medical oversight and quality assurance of EMS providers, even during an emergency, to help assure patient safety.
- **Institutional autonomy.** If organizations and institutions cede their authority in order to participate in a unified incident management system in a crisis, the plan may have to address the legal implications for those organizations.
- **Facility standards.** Standards of care that pertain to space, equipment, and physical facilities may have to be altered in both traditional medical care facilities and alternate care sites that are created in response to the event.
- **Patient privacy and confidentiality.** Provisions of HIPAA and other laws and regulations that require signed releases and other measures to ensure privacy and confidentiality of a patient's medical information may have to be altered.
- **Documentation of care.** Minimally accepted levels of documentation of care provided to an individual may have to be established, both for purposes of patient care quality and as the basis for reimbursement from third-party payers.
- **Property seizures.** Provisions may have to be made to take over property, including facilities, supplies, and equipment for the delivery of care or to destroy property deemed unsafe.
- **Provisions for quarantine or mass immunization.** The plan may have to address the establishment and enforcement of isolation, quarantine and mass immunization and provisions for release or exception.

Any waivers granted are likely to be targeted to the affected area for a temporary and specified period of time and scope. In the case of a mass casualty event such as pandemic influenza that involves a communicable agent that moves from region to region, it will be important to have flexibility to extend or expand such waivers.