PUBLIC HEALTH EMERGENCY DECLARATION
QUESTIONS AND ANSWERS

Under section 319 of the Public Health Service (PHS) Act, the Secretary of the Department of Health and Human Services ("Secretary") can declare a public health emergency ("PHE"). Questions have arisen from states, political subdivisions, and the healthcare community regarding PHE declarations.

The following is not an exhaustive review of section 319 of the PHS Act or of PHE declarations in all contexts, nor a protocol for the Department of Health and Human Services' (HHS) implementation of a PHE declaration.

Overview

Under section 319 of the PHS Act, the Secretary can declare a PHE if he determines, after consulting with such public health officials as may be necessary, that 1) a disease or disorder presents a PHE or 2) a PHE, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists. A PHE declaration allows the Secretary to take certain actions in response to the PHE. In addition, a public health emergency can be a necessary step in authorizing the Secretary to take a variety of discretionary actions to respond to the PHE under the statutes HHS administers.

1. What actions may the Secretary take under section 319 of the PHS Act when he declares a PHE?

Under section 319 of the PHS Act, when the Secretary has declared a PHE, consistent with his other statutory authorities, he can take such action as may be appropriate to respond to the PHE including making grants; entering into contracts; and conducting and supporting investigations into the cause, treatment, or prevention of the disease or disorder. In addition, the Secretary may access funds appropriated to the Public Health Emergency Fund (although currently there are no funds appropriated to this Fund). Finally, the Secretary may grant extensions or waive sanctions relating to submission of data or reports required under HHS laws, when the Secretary determines that as a result of the PHE, individuals or public or private entities are unable to comply with deadlines for such data or reports.

2. What other discretionary actions may the Secretary take to respond to a PHE that require a PHE declaration?

A PHE declaration can be a necessary step in enabling the Secretary to take a variety of discretionary actions to respond to the PHE. Certain authorities have been added to the PHS Act; the Social Security Act (SSA); the Federal Food, Drug, and Cosmetic Act (FFDCA); and other laws administered by the Secretary that permit the Secretary to take certain actions when he has declared a PHE under section 319 of the PHS Act.

For example, the Secretary may:

- Waive or modify certain Medicare, Medicaid, State Children's Health Insurance Program (SCHIP) and Health Insurance Portability and Accountability Act (HIPAA) requirements. Under section 1135 of the SSA, the Secretary may waive or modify certain requirements as necessary to ensure to the maximum extent feasible that, in an emergency area during an emergency period, sufficient health care items and services are available to meet the needs of individuals enrolled in SSA programs (including Medicare, Medicaid, and SCHIP) and that providers of such services in good faith who are unable to comply with certain statutory requirements are reimbursed and exempted from sanctions for noncompliance, absent fraud or abuse. There must also be a Presidential declaration of an emergency or disaster in order to exercise this authority. See the response to items 3-6 below for details about this authority.
- Exempt for 30 days a person from select agents requirements as necessary to provide for timely participation of the person in a response to a domestic or foreign public health emergency that involves the select agent or toxin (the Secretary may also exercise this authority in an emergency without formally declaring a PHE).
- Waive certain prescription and dispensing requirements. Under section 505-1(f) of the FFDCA, the Food and Drug Administration (FDA) has the authority to require Risk Evaluation and Mitigation Strategies (REMS) for a prescription drug as necessary to assure safe use of the drug, because of its inherent toxicity or potential harmfulness, if FDA determines that the drug is effective but is associated with a serious adverse drug experience, and could not be approved (or approval would be withdrawn) without the required elements to mitigate the risk and other potential REMS elements are not sufficient to mitigate the risk. For example, FDA may require: certification of health care providers or of dispensers (pharmacies, practitioners, health care settings); dispensing only in certain settings, e.g., hospitals; dispensing with certain documentation, e.g., lab results; patient monitoring; and patient registries. When the Secretary has declared a PHE, he may waive these requirements during the PHE with respect to a qualified countermeasure to which such a requirement has been applied when the waiver is needed to mitigate the effects of, or reduce the severity of, the emergency.
- Adjust Medicare reimbursement for certain Part B drugs. Most Medicare Part B drugs are paid on the basis of the manufacturer's average sales price (ASP), which manufacturers are required to report quarterly. The ASP-based payment allowance is updated prospectively each quarter, using the data manufacturers report. The statutory scheme results in a two-quarter lag between the date of the reported sale and the date that sale's price is factored into the Medicare payment rate. In the case of a PHE in which there is a documented inability to access drugs and biologicals and a concomitant increase in the price of a drug or biological that is not reflected in the manufacturer's ASP for one or more quarters, the Secretary may use the wholesale acquisition cost or other reasonable measure of drug or biological price instead of the manufacturer's ASP. The substituted price or measure may be used until the price of the drug or biological has stabilized and is substantially reflected in the manufacturer's ASP.

- Waive certain Ryan White HIV/AIDS grant program requirements. Under section 2683 of the PHS Act, up to five percent of the funds available under each of the Parts A and B base supplemental pools may be shifted to ensure access to care during the time period when the Secretary declares a PHE or when the President declares an emergency or major disaster under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("Stafford Act") or the National Emergencies Act in the geographic area where the emergency, major disaster, or PHE exists. In addition, the Secretary may waive such requirements of title XXVI of the PHS Act, which addresses health care services related to HIV infection, to improve the health and safety of those receiving care under this title and the general public. This waiver authority is limited to the time period for which the emergency, major disaster, or PHE declaration exists.
- Make temporary (up to one year or the duration of the emergency) appointments of personnel to positions that directly respond to the PHE when the urgency of filling positions prohibits examining applicants through the competitive process. The Secretary may also waive dual compensation (salary offset) for temporarily re-employed annuitants during the time period when the Secretary declares a PHE or the President declares a national emergency involving a direct threat to life or property or other unusual circumstances.
- Declare an emergency under section 564 of the FFDCA justifying an emergency use authorization (EUA) of unapproved drugs, devices, or biological products, or emergency use authorization of approved drugs, devices, or biological products for an approved use. An EUA may be used to authorize use of investigational vaccines and other countermeasures. Before declaring an emergency under section 564, the Secretary must determine that a PHE under section 319 of the PHS Act exists that affects, or has a significant potential to affect national security, and that involves a specified chemical, biological, radiological, or nuclear (CBRN) agent or agents, or a specified disease or condition that may be attributable to such agent or agents. The Secretary's declaration of an emergency under section 564 of the FFDCA can alternatively be based on a: a) determination by the Secretary of Homeland Security that there is an actual or significant potential for a domestic emergency involving heightened risk of attack with an CBRN agent; or b) determination by the Secretary of the Department of Defense that there is an actual or significant potential for a military emergency involving heightened risk of attack to U.S. military forces with a CBRN. For more information about EUAs, please see Food and Drug Administration Guidance, *Emergency Use Authorization of Medical Products*, available at http://www.fda.gov/oc/guidance/emergencyuse.html.

3. In addition to a PHE declaration, what other conditions are necessary for the Secretary to waive or modify certain Medicare, Medicaid, SCHIP, and HIPAA requirements under section 1135 of the SSA?

The Secretary may exercise his authority under section 1135 of the SSA ("1135 waiver") to temporarily waive or modify certain Medicare, Medicaid, SCHIP, and HIPAA requirements in an emergency area during the emergency period. An emergency area and

period is where and when there is: a) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the Stafford Act, *and* b) a PHE declared by the Secretary.

4. When the Secretary issues an 1135 waiver what Medicare, Medicaid, SCHIP, and HIPAA requirements may be temporarily waived or modified?

Under section 1135 of the SSA, the following Medicare, Medicaid, SCHIP and HIPAA requirements may be waived or modified:

- Conditions of participation or other certification requirements, or program participation and similar requirements for individual providers or types of providers.
- Pre-approval requirements for providers or health care items or services.
- Requirements that physicians and other health care professionals hold licenses in the State in which they provide services if they have a license from another State and are not affirmatively barred from practice in that State or any State in the emergency area (note however, that this waiver is for the purposes of Medicare, Medicaid, and SCHIP reimbursement only – states determine whether a non-Federal provider is authorized to provide services in the state without state licensure).
- Sanctions under the Emergency Medical Treatment and Active Labor Act (EMTALA) for redirection of an individual to another location to receive a medical screening examination pursuant to a state emergency preparedness plan or transfer of an individual who has not been stabilized if the transfer arises out of the circumstances of the emergency. A waiver of EMTALA sanctions is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay. EMTALA waivers are subject to special time limits. See question 6 for more information.
- Sanctions related to Stark self-referral prohibitions which could apply when a physician refers a patient for services to a provider in which the physician has a financial interest.
- Deadlines and time tables for performance of required activities to allow timing of such deadlines to be modified.
- Limitations on payments to permit Medicare+Choice enrollees to use out-of-network providers in an emergency situation. To the extent possible, the Secretary must reconcile payments so that enrollees do not pay additional charges and so that the plan pays for services included in the capitation payment.
- Sanctions and penalties arising from noncompliance with HIPAA privacy regulations relating to: a) obtaining a patient's agreement to speak with family members or friends or honoring a patient's request to opt out of the facility directory, b) distributing a notice of privacy practices, or c) the patient's right to request privacy restrictions or confidential communications. The waiver of HIPAA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay. These HIPAA waivers under are subject to special time limits. See question 6 for more information.

5. If the Secretary issues an 1135 waiver, are the Medicare, Medicaid, SCHIP and HIPAA requirements listed above automatically waived or modified upon issuance of the 1135 waiver document?

No, in past practice when the Secretary has issued an 1135 waiver, the Medicare, Medicaid, and SCHIP requirements that may be waived or modified under that 1135 waiver are not automatically waived or modified. Rather, the Centers for Medicare & Medicaid Services (CMS) receive requests from affected hospitals, health care facilities, and health care providers for waivers or modifications of specific requirements and issues instructions or guidance as needed. CMS reviews such requests and generally approves the requested waivers or modifications on a case by case basis. Regardless of whether the Secretary has made a formal PHE declaration under Section 319 of the PHS Act, and even in the absence of an 1135 waiver, other SSA provisions and CMS regulations may provide certain flexibilities that may be implemented as appropriate to address an emergency or disaster. CMS works closely with affected hospitals, health care facilities, and health care providers during such situations to address their concerns.

With regards to the HIPAA sanctions and penalties that may be temporarily waived under section 1135 of the SSA, when the Secretary issues an 1135 waiver, HHS' current practice is to automatically waive such sanctions and penalties described in the 1135 waiver in the emergency area for 72 hours beginning on implementation of a hospital disaster protocol. The waiver of HIPAA requirements is effective only if actions under the waiver do not discriminate on the basis of a patient's source of payment or ability to pay. Also, the waiver only applies if the hospital has implemented its hospital disaster protocol. The HIPAA sanctions and penalties that may be waived when an 1135 waiver is issued are specified in the 1135 waiver document. An 1135 waiver does not waive HIPAA in its entirety. Even without an 1135 waiver, there are various flexibilities and exceptions that may apply to permit covered entities to share protected health information during a PHE. Please see http://www.hhs.gov/ocr/hipaa/emergencyPPR.html for more information about the application of HIPAA during public health emergencies (whether or not the Secretary makes a formal PHE declaration under section 319 of the PHS Act, or issues an 1135 waiver).

6. When the Secretary waives or modifies certain Medicare, Medicaid, SCHIP, and/or HIPAA requirements under section 1135 of the SSA, how long are such waivers or modifications applicable?

Waivers or modifications under section 1135 of the SSA may be retroactive to the beginning of the emergency period (or to any subsequent date). The waiver or modification terminates either upon termination of the emergency period or 60 days after the waiver or modification is first published (subject to 60-day renewal periods until termination of the emergency). However, waivers of EMTALA (except in the case of a pandemic disease) or HIPAA requirements are effective only for 72 hours beginning on implementation of a hospital disaster protocol. A waiver of EMTALA sanctions in

connection with an emergency involving a pandemic disease (such as pandemic influenza) is effective until the termination of the pandemic-related public health emergency. However, a particular waiver or modification will terminate prior to the ultimate termination date described in this paragraph (e.g., prior to the 72 hour time period after a hospital begins to implement its disaster protocol) if the Secretary determines that as of an earlier date, the waiver or modification is no longer necessary to accomplish the purposes set forth in Section 1135(a).

7. How long does a PHE declaration last?

A PHE declaration lasts until the Secretary declares that the PHE no longer exists or upon the expiration of the 90-day period beginning on the date the Secretary declared a PHE exists, whichever occurs first. The Secretary may extend the PHE declaration for subsequent 90-day periods for as long as the PHE continues to exist, and may terminate the declaration whenever he determines that the PHE has ceased to exist.

8. Is a PHE declaration required in order for HHS to provide assistance to states and political subdivisions during a PHE or other incident?

Even without a PHE declaration, the Secretary has broad legal authority to provide assistance to states and to conduct research studies. For example, under section 301 of the PHS Act, the Secretary has broad authority to render assistance and promote research, investigations, demonstrations, and studies into the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man. Similarly, under section 311 of the PHS Act, the Secretary is authorized to assist states and their political subdivisions in the prevention and suppression of communicable diseases and to develop (and take necessary actions to implement) a plan under which personnel, equipment, medical supplies, and other resources of the Public Health Service and other agencies under the jurisdiction of the Secretary may be effectively used to control the epidemics of any disease or condition and to meet other health emergencies or problems. The Secretary may also activate the National Disaster Medical System and deploy the Strategic National Stockpile without a PHE declaration.

9. Does a PHE declaration waive or preempt state licensing requirements for healthcare providers?

No, a PHE declaration does not waive or preempt state licensing requirements. States determine whether and under what circumstances a non-Federal healthcare provider is authorized to provide services in the state without state licensure.

As discussed in response #4 above, when the Secretary issues an 1135 waiver, the Secretary may waive Medicare, Medicaid or SCHIP requirements that physicians and other health care professionals hold licenses in the State in which they provide services. This would be for Medicare, Medicaid or SCHIP reimbursement purposes only, and would apply only if the physicians or other health care providers have an equivalent

license from another State (and are not affirmatively barred from practice in any State in the emergency area).

10. Is a PHE required for the Secretary to provide liability immunity under the Public Readiness and Emergency Preparedness (PREP) Act?

No. Under the PREP Act, Pub. L. No. 109-148, the Secretary may issue a declaration that provides tort liability immunity (except for willful misconduct) for claims of loss caused, arising out of, relating, to, or resulting from administration and use of countermeasures to diseases, threats and conditions determined by the Secretary to constitute a present, or credible risk of a future public health emergency to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of such countermeasures. A PREP Act declaration is independent of a PHE declaration, and the Secretary does not have to declare a PHE to issue a PREP Act declaration or for liability immunity under the PREP Act to take effect. For more information about the PREP Act, please see http://www.hhs.gov/disasters/emergency/manmadedisasters/bioterorism/medication-vaccine-qa.html

11. Does a state governor or other entity have to make a formal request for a PHE or for an 1135 waiver?

No, there is no requirement under section 319 of the PHS Act, nor under section 1135 of the SSA that a state or other entity make a formal request for a PHE declaration or an 1135 waiver. When state or local officials believe that a PHE declaration and 1135 waivers are needed to assist the response to a particular event, HHS encourages them to work with the HHS Regional Emergency Coordinator at the HHS regional office in their area who can help facilitate the request. Hospitals, healthcare entities, and health care providers who have concerns about Medicare, Medicaid, and SCHIP requirements should contact the CMS regional office in their area who can help address such concerns.

12. May the Secretary declare a "potential" PHE?

No, the statutory language in section 319 of the PHS Act does not address a "potential" or threat of a PHE. However, the Secretary has the discretion to determine that a disease or condition "presents" a PHE, or a PHE otherwise exists, based on conditions that exist prior to the actual outbreak of disease or natural catastrophe. For example, the Secretary may declare a PHE based on emergency needs that exist preceding the outbreak of disease, or in anticipation of a storm before a hurricane makes landfall.

13. How does a PHE declaration relate to a Presidential declaration of an emergency or major disaster under the Stafford Act?

A PHE declaration under section 319 of the PHS Act and a Presidential declaration of an emergency or disaster under the Stafford Act are distinct and separate declarations.

When an incident overwhelms or is anticipated to overwhelm State resources, the Governor may request Federal assistance, including assistance under the Stafford Act.[1] The Stafford Act authorizes the President to provide financial and other assistance to State and local governments, certain private nonprofit organizations, and individuals to support response, recovery, and mitigation efforts following Presidential emergency or disaster declarations.

The Stafford Act is triggered by a Presidential declaration of a major disaster or emergency, when an event causes damages of sufficient severity and magnitude to warrant Federal disaster assistance to supplement the efforts and available resources of States, local governments, and the disaster relief organizations in alleviating the damage, loss, hardship, or suffering. Most incidents are not of sufficient magnitude to warrant a Presidential declaration. However, if State and local resources are insufficient, a Governor may ask the President to make such a declaration. Ordinarily only a Governor can initiate a request for a Presidential emergency or major disaster declaration. In extraordinary circumstances, the President may unilaterally declare a major disaster or emergency.

Unlike a Presidential declaration of a major disaster or emergency under the Stafford Act which ordinarily requires a formal request by a state Governor, there is no requirement that a Governor or other entity make a formal request in order for the Secretary to declare a PHE under section 319 of the PHS Act. The President may declare a major disaster or emergency under the Stafford Act in the absence of a Secretarial declaration of a PHE under section 319 of the PHS Act. Likewise, the Secretary of HHS may declare a PHE under section 319 of the PHS Act in the absence of a Presidential declaration under the Stafford Act.

While a Presidential declaration under the Stafford Act and a Secretarial declaration of a PHE are separate declarations, sometimes a Stafford Act declaration is required in order for the Secretary to exercise certain authorities. For example, as discussed in the response to item #3 above, in order for the Secretary to exercise his waiver authority under section 1135 of the SSA to temporarily waive or modify certain Medicare, Medicaid, SCHIP, and HIPAA requirements, there must be a PHE declaration in place, as well as a Presidential declaration of a major disaster or emergency pursuant to the Stafford Act (or the National Emergencies Act).

[1] See the Department of Homeland Security National Response Framework, pages 42 (January 2008). Details regarding Federal involvement under the Stafford Act are available at the National Response Framework Resource Center, http://www.fema.gov/NRF. Additional information about the Stafford Act's disaster process and disaster aid programs is available at http://www.fema.gov/hazard/dproc.shtm.