

## Public Health Service Act, Section 319 Public Health Emergencies Fact Sheet

### Overview

The Public Health Service Act (PHSA)<sup>1</sup> provides the legal authority for the Department of Health and Human Services (HHS), among other things, to respond to public health emergencies. The Act authorizes the HHS Secretary to lead federal public health and medical response to public health emergencies, determine that a public health emergency exists, and assist states in their response activities. This fact sheet focuses on Section 319 of the PHSA which governs public health emergencies.

### What the Law Does

Section 319 authorizes the Secretary to determine that a public health emergency exists. This determination triggers emergency powers that permit the federal government to engage in activities such as assisting state and local governments, suspending or modify certain legal requirements, and expending available funds to address the public health emergency.

### How the Law Works

#### ***Determination of Public Health Emergency***

Section 319 authorizes the Secretary to make a determination that a public health emergency exists if the Secretary determines that a disease or disorder presents a public health emergency or a public health emergency—including significant outbreaks of infectious diseases or bioterrorist attacks—otherwise exists.<sup>2</sup> The Secretary's action is specifically referred to as a "determination" in Section 319 and in documents issued by HHS instead of the term "declaration". The Secretary can determine that a disease or condition presents a public health emergency based on conditions existing before an outbreak or natural disaster occurs.<sup>3</sup>

Although a Section 319 determination activates certain federal emergency powers, a public health emergency determination is not required in order for HHS to assist states; the Secretary has broad legal authority under other sections of the PHSA to render assistance to states and localities. PHSA Section 301 gives the Secretary broad authority to provide assistance and conduct investigations, among other things, into the causes, prevention, and control of diseases.<sup>1</sup> PHSA Section 311 permits the Secretary to work with states and localities to prevent and control communicable diseases and to implement plans activating HHS resources to control diseases and other public health emergencies.<sup>1</sup> The Secretary can activate the National Disaster Medical System and deploy the Strategic National Stockpile without a Section 319 determination.

#### ***Authorities Granted***

Once the HHS Secretary determines that a public health emergency exists, the Secretary is authorized, consistent with the Secretary's other authorities, to respond to the public health emergency. These authorities include making grants, contracting, and investigating the cause, treatment, or prevention of the disease or disorder underlying the public health emergency. The Secretary may use funds from the Public Health Emergency Fund when funds are appropriated for it.

Over time Congress has added other authorities to the PHSA, the Social Security Act (SSA), the Federal Food, Drug and Cosmetic Act (FFDCA), and other laws administered by the Secretary that allow the Secretary to take certain discretionary actions once a public health emergency determination is made under Section 319. Other discretionary actions include:

- Using SSA Section 1135 to waive or modify certain requirements under Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and Health Insurance Portability and Accountability Act (HIPAA).
- Exempting a person from select agents requirements for 30 days.
- Waiving certain prescription and dispensing requirements under the FFDCA.
- Adjusting Medicare reimbursement for certain Part B drugs.
- Waiving certain Ryan White HIV/AIDS grant program requirements.

- Making temporary personnel appointments up to one year.
- Granting extensions or waiving sanctions relating to submission of data or reports.<sup>3</sup>

### Duration

A Section 319 determination remains in effect for 90 days or until the Secretary determines that the emergency no longer exists, whichever occurs first. If the same or additional conditions continue to warrant a public health emergency, the Secretary may renew the determination for additional 90-day periods.

### Relationship to Other Emergency Laws

- **Stafford Act and National Emergencies Act** - A public health emergency determination under Section 319 of the PHSA is separate and distinct from a Presidential declaration of emergency under the National Emergencies Act or a Stafford Act declaration of an emergency or disaster. The HHS Secretary does not need a Presidential declaration to issue a public health emergency determination under Section 319. Unlike a Stafford Act declaration which must be initiated by a gubernatorial request to the President, the Secretary can make a Section 319 public health emergency determination without a state request.

Declarations under other laws are required for the Secretary to exercise certain authorities. In order for the Secretary to exercise waiver authority under SSA Section 1135 there must be an existing public health emergency declaration in addition to a Presidential declaration under the Stafford Act or the National Emergencies Act.

- **PREP Act** - The Secretary does not need to make a public health emergency determination under PHSA Section 319 in order to issue a declaration under the Public Readiness and Emergency Preparedness Act (PREP Act) for the liability immunity under the PREP Act to go into effect. The PREP Act, among other things, allows the Secretary to provide tort liability immunity (except for willful misconduct) for claims of loss arising from the development and administration of countermeasures against diseases or threats that constitute a current or future risk of public health emergency.

#### Practice Notes

- Identify circumstances in which your state might want or need a §319 determination.
- Identify the legal and programmatic affects a §319 determination have in your state.
- Understand what, if any, affects a §319 determination will have on your state's response and emergency legal authorities with and without a state emergency declaration.
- Identify the process your state or health agency should use in requesting federal assistance.

### Immunity and Liability Issues

Section 319 does not contain any immunity provisions or liability protections. The determination of a public health emergency, however, is a prerequisite for the activation of liability provisions in other laws such as the PREP Act.

### How the Law Affects States

A determination by the HHS Secretary under Section 319 that a public health emergency exists activates the Secretary's emergency powers to provide states with resources and personnel to respond to the emergency and to waive or modify certain legal requirements. There is no statutory or regulatory requirement that a state submit a formal request to the Secretary for the determination of a public health emergency under PHSA Section 319 or a SSA Section 1135 waiver to be made. HHS encourages states to work with regional emergency coordinators in HHS regional offices to facilitate the request if the state believes such determinations are needed to respond to an event.<sup>3</sup> A state declaration of emergency does not affect the Secretary's Section 319 authority to determine that a public health emergency exists. However, the fact that a state has declared an emergency or requested federal assistance in response to an emergency may be relevant to the Secretary's consideration of whether a public health emergency exists.

#### Sources

<sup>1</sup> Public Health Service Act, Pub. L. No. 104-321; Codified at 42 U.S.C. § 247d.

<sup>2</sup> Centers for Disease Control and Prevention, Public Health Law Program. "Selected Federal Legal Authorities Pertinent to Public Health Emergencies". September 2009. Available at <https://www.cdc.gov/phlp/docs/ph-emergencies.pdf>. August 2017. Accessed October 26, 2017.

<sup>3</sup> Department of Health and Human Services. "Public Health Emergency Declaration Q&A's" webpage. Available at: [www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx](http://www.phe.gov/Preparedness/legal/Pages/phe-qa.aspx). Accessed October 26, 2017.

This document was compiled from June–December 2011 and reflects the laws and programs current then. It reflects only portions of the laws relevant to public health emergencies and is not intended to be exhaustive of all relevant legal authority. This resource is for informational purposes only and is not intended as a substitute for professional legal or other advice. The document was funded by CDC Award No. 1U38HM000454 to the Association of State and Territorial Health Officials; Subcontractor PI Elliott, Logan Circle Policy Group LLC.