



# appendix E: legal authorities

## Legal authorities

Numerous Federal and state statutes authorize relevant public health actions to address pandemic influenza. Knowledge of these authorities is essential for planning and implementing an effective response to an influenza pandemic.

Section 319(a) of the Public Health Service (PHS) Act (42 U.S.C. 247d), authorizes the HHS Secretary to declare a public health emergency and "take such action as may be appropriate to respond" to that emergency consistent with existing authorities. Appropriate action may include, as otherwise authorized, making grants, providing awards for expenses, entering into contracts, and conducting and supporting investigation into the cause, treatment, or prevention of the disease or disorder that presents the emergency. The Secretary's declaration also can be the first step in authorizing emergency use of unapproved products or approved products for unapproved uses under section 564 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3), or waiving certain regulatory requirements of the Department, such as select agents requirements, or—when the President also declares an emergency—waiving certain Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) provisions. Under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 et seq.), the Federal Emergency Management Agency (FEMA), Department of Homeland Security, is authorized to coordinate the activities of Federal agencies in response to a Presidential declaration of a major disaster or emergency, with HHS having the lead for health and medical services. The President may also declare an emergency under the National Emergencies Act (50 U.S.C. 1601 et seq.)

The PHS Act provides additional authorities for core activities of HHS that will be needed to plan and implement an emergency response. For example, Sections 301, 319F-1, 402, and 405 of the PHS Act authorize the HHS Secretary to conduct and support research. Section 351 of the PHS Act and provisions of the Federal Food, Drug, and Cosmetics Act authorize the Secretary and the FDA to regulate vaccine development and production. Infrastructure support for preventive health services such as immunization activities, including vaccine purchase assistance, is provided under section 317 of the PHS Act. Section 319F-2 of the PHS Act authorizes the Secretary, in coordination with the Secretary of Homeland Security, to maintain the Strategic National Stockpile.



Section 361 authorizes the Secretary to make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States, or from one state or possession into any other State or possession. CDC administers these regulations as they relate to quarantine of humans. Diseases for which individuals may be quarantined are specified by Executive Order; the most recent change to the list of quarantinable diseases was the April 1, 2005 Executive Order 13375, which amended the Executive Order 13295 by adding "influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic" to the list. Other provisions in Title III of the PHS Act permit HHS to establish quarantine stations, provide care and treatment for persons under quarantine, and provide for quarantine enforcement. Section 311 of the PHS Act provides for Federal-state cooperative activities to enforce quarantine and plan and carry out public health activities. Section 311 also authorizes the Secretary to make available the resources of the PHS to help control epidemics and deal with other public health emergencies. HHS may also engage in certain international activities under section 307 of the PHS Act. Statute 42 U.S.C. § 97, which provides that the Secretary of Health and Human Services may request that Customs, Coast Guard, and military officers aid in the execution of quarantines imposed by states. The Secretary also has the authority to implement disease control measures in Indian country, if necessary. (25 U.S.C. 198, 231; 42 U.S.C. 2001). Indian Tribes, like states, are sovereign entities with police power authority to enact their own disease control rules and regulations. Tribal law should be consulted as well.

Further, HHS has broad authority to coordinate vaccine development, distribution, and use activities under section 2102 of the PHS Act, describing the functions of the National Vaccine Program. The Secretary has authority for health information and promotion activities under Title XVII and other sections of the PHS Act. HHS can provide support to states and localities for emergency health planning under Title III of the PHS Act.

Both Federal and state statutes may apply to specific interventions that would be implemented to control a pandemic. Key issues and relevant Federal authority are shown in Table E-1. States should review their authorities to respond to a public health emergency and to take necessary actions for its control.

**Table E-1. Key Pandemic Response Components and Legal Authorities.**

Issue	Authority
<ul style="list-style-type: none"> <li>■ Public sector vaccine or antiviral drug purchase</li> </ul>	<ul style="list-style-type: none"> <li>■ Antivirals have been added to the Strategic National Stockpile.</li> <li>■ At the time of a pandemic, the Federal Government could consider purchasing vaccine or antiviral drugs, if available.</li> </ul>
<ul style="list-style-type: none"> <li>■ Indemnification of manufacturers</li> </ul>	<ul style="list-style-type: none"> <li>■ Executive Order 10789, as amended by Executive Order 13232, extends authorities under P.L. 85-804 to HHS to use indemnification provisions of the Federal Acquisition Regulations, 48 C.F.R. 50.403, if the contractor performs an activity that involves unusually hazardous risks and insurance is not available or sufficient to cover those risks. A contracting officer must review a request for indemnification, and the Secretary must personally approve the request and in some cases consult with Department of Homeland Security and the Office of Management and Budget.</li> <li>■ Other relevant, but more limited, indemnification authorities such as section 301(a)(7) of the PHS Act may also be available.</li> </ul>

**Table E-1. Continued**

Issue	Authority
<ul style="list-style-type: none"> <li>■ Distribution of vaccines or antiviral drugs and liability protections</li> </ul>	<ul style="list-style-type: none"> <li>■ The Federal Government may mobilize the PHS Commissioned Corps to distribute vaccines or medications to Federal agencies with direct patient care responsibilities, or to states, tribes, and other localities through the National Disaster Medical System and through agreements between the Federal government, states, and localities. Provision of the medication by particular health care providers is a matter of state law.</li> <li>■ If a Federal employee administers an antiviral medication or vaccine in the course of his/her official duties, the employee is covered under section 224 of the PHS Act, which makes the Federal Tort Claims Act the exclusive remedy.</li> <li>■ If the provider were a Federal contractor generally, the contractor would be expected to carry malpractice insurance; expenses of purchasing such insurance generally are an allowable cost of the contract.</li> <li>■ State employees may be covered for malpractice or tort claims coverage under state law. States should consult their laws on this matter.</li> <li>■ Private sector employees would generally carry private malpractice insurance. They may also be covered by the Volunteer Protection Act, State Good Samaritan Act, or State Emergency compact provisions.</li> </ul>
<ul style="list-style-type: none"> <li>■ Compensation for persons injured by vaccine or antiviral medications</li> </ul>	<ul style="list-style-type: none"> <li>■ If a person is injured following administration of a vaccine or antiviral medication, in connection with his/her employment, compensation may be available under a state's worker's compensation program. For Federal employees, compensation may be available under the Federal Employees' Compensation Act.</li> </ul>
<ul style="list-style-type: none"> <li>■ Measures to decrease the transmission of infection</li> </ul>	<ul style="list-style-type: none"> <li>■ Individuals may be denied admission to the U.S. if thought to have a communicable disease of public health significance, as defined in CDC regulations. Individuals also may be isolated or quarantined by the Federal Government, or restricted from moving within or between states, if thought to have been exposed to or to be a source of infections to others of a communicable disease listed in an executive order signed by the President.</li> <li>■ State governors generally may restrict travel within their states and access to their states. Individual state law should be consulted to determine permissible exercise of this authority.</li> <li>■ States also may impose quarantine. The Secretary may aid states and localities in enforcement of their quarantine actions and accept state and local assistance in enforcing Federal quarantine.</li> <li>■ In settings such as long-term care facilities where there are public health risks associated with spread of a pandemic strain, states also may be able to compel an individual to take antiviral prophylaxis or be vaccinated, as circumstances warrant. State law should be consulted.</li> </ul>