Health care and emergency workers will be among the first to receive vaccinations for smallpox under the Bush Administration's plans to prepare for a bioterrorist attack.

The Centers for Disease Control and Prevention have reviewed vaccination plans submitted by each state under a December 9 deadline. These plans contain information on the number of people comprising each public health smallpox and health care smallpox response team, information on where vaccines would be administered, the number of health care facilities identified to participate, and the number of clinics needed to support this effort.

According to the CDC’s review of the plans, close to 450,000 public health and health care personnel may be offered the vaccine when it becomes available. The plan is voluntary and eligible individuals will make their own decision on whether or not to receive the vaccine. Hundreds of clinics around the nation would be set up to deliver the vaccine to those who choose to receive it. In addition, state health officials have identified over 3,300 health care facilities that would participate in the program.

Immunizing 500,000 health care workers will present huge logistical challenges. Most doctors now in practice have had no experience with making the 15 scratches used in administering the vaccine to the skin, and relatively few have treated, or seen, the complications that can occur. Sore arms, fever and swollen lymph nodes are common after a vaccination. Doctors must examine vaccine recipients to ensure that their reactions are the expected ones that require no treatment, not secondary infections that may require antibiotics.

Due to the nature of the vaccine, many people may be expected to suffer some degree of physical reaction, including some possible deaths. To avoid widespread absenteeism and staffing shortages due to vaccine reactions, the Administration reportedly is asking hospitals to schedule the vaccinations in stages. Another logistical problem with the vaccination plans is how to screen potential recipients for medical conditions that could disqualify them.

Health Care Facilities Administering Vaccine Will Have Risk Protection

The sizeable risks involved with administering the smallpox vaccine are addressed in the recently enacted Homeland Security Act. The Act contains provisions for the administration of the smallpox vaccine by “health professionals” pursuant to a declaration of the Secretary of Health and Human Services. Under Section 304, “Conduct of Certain Public Health-Related Activities,” hospitals and other health care providers acting pursuant to such a declaration in administering the vaccine will not be liable for resulting death or injury.

With respect to liability, the Act deems the individuals administering the vaccine within the prescribed parameters to be employees of the Public Health Service. As the Act states, “the United States shall be liable under this subsection with respect to a claim arising out of the administration of a covered countermeasure to an individual during the effective period of a declaration,” where the covered countermeasure is the smallpox vaccine. Such countermeasure must have been administered by a “qualified person,” meaning “a licensed health professional or other individual who is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered.” The qualified person must have had reasonable grounds to believe the individual receiving the vaccine was within a category of individuals covered by the declaration.
The Act provides the exclusive remedy for any claim arising from the administration of the vaccine within the specified parameters. To proceed with a claim under the Act against the United States, the Attorney General must certify that the action is against a “covered person” and is based on a claim alleging personal injury or death arising out of the administration of the “covered countermeasure.” A “covered person” is any person who is (a) a manufacturer or distributor of such countermeasure; (b) a health care entity under whose auspices such countermeasure was administered; (c) a qualified person who administered such countermeasure; or (d) an official, agent, or employee of such a person.

CDC Smallpox Related Questions and Answers on Homeland Security Act
The Centers for Disease Control and Prevention has posted a series of questions and answers regarding the liability concerns of health care entities administering the smallpox vaccine under the Homeland Security Act. The following “Smallpox Questions and Answers: Section 304 of the Homeland Security Act” (.PDF file/108 Kib/3 pgs.), are also available on the CDC website at:

Q.1. What is the purpose of Section 304 of the Homeland Security Act?

A.1. Manufacturers of smallpox vaccine and those healthcare entities that would administer the vaccine have raised concerns about their potential liability for involvement in a federal smallpox vaccination campaign. Section 304 of the Homeland Security Act is intended to alleviate these liability concerns and therefore ensure that vaccine is available and can be administered, particularly in the event of a smallpox-related actual or potential public health emergency such as a bioterrorist incident.

Q.2. In general, what does Section 304 provide?

A.2. Section 304 provides an exclusive remedy against the United States for injury or death attributable to smallpox vaccine, other substances used to treat or prevent smallpox, or vaccinia immune globulin (“smallpox countermeasures”). This means that no claim for liability for injury or death attributable to a smallpox countermeasure could be brought against entities or individuals who are covered by Section 304’s protections.

Q.3. When do the provisions of Section 304 become effective?

A.3. The effective date, as established in Section 4 of the Homeland Security Act, is January 24, 2003. If vaccination is to begin sooner, Section 304 would apply at that earlier time only if Congress enacts legislation moving up the effective date.

Q.4. If I am injured as a result of receiving a smallpox countermeasure, how do I know if I can file a Section 304 claim?

A.4. Section 304 is triggered if and when a smallpox countermeasure is administered pursuant to a declaration by the Secretary of Health and Human Services. The declaration will specify the administration of particular countermeasures to one or more categories of individuals, and it will state how long it is in effect. An individual described in the declaration who receives one of those countermeasures from a qualified person while the declaration is in effect, and who is injured as a result, may file a claim under Section 304.

Q.5. Who is a “qualified person?”

A.5. Qualified persons are licensed health professionals or other individuals authorized to administer smallpox countermeasures under state law. Section 304 claims may be filed for injuries due to administration of countermeasures only if the countermeasure is administered by a qualified person.

Q.6. If I contract vaccinia without having received smallpox vaccine, can I file a Section 304 claim?

A.6. Individuals who were not inoculated, but who nonetheless contract vaccinia during the period of the Secretary’s declaration or 30 days thereafter, or who reside or resided with an individual who was inoculated pursuant to the declaration, may submit claims.

Q.7. What is the process for filing a Section 304 claim?

A.7. Anyone who believes he or she has a claim for money damages attributable to injury or death due to smallpox countermeasures must submit an administrative claim with an appropriate agency of the United States within two years. If the agency denies the claim, or if no action is taken on the claim within six months, the injured individual may file suit in
Q.8. May the Secretary make the declaration prior to the occurrence of a bioterrorist incident or public health emergency?

A.8. A declaration can be made if the Secretary concludes that an actual or potential bioterrorist incident or other actual or potential public health emergency makes the administration advisable. The Secretary can, therefore, make the declaration prior to the occurrence of a bioterrorist incident or public health emergency.

Q.9. What entities are covered by Section 304’s protections?

A.9. With respect to administration of a covered countermeasure, manufacturers and distributors of countermeasures, healthcare entities under whose auspices the countermeasure is administered, and licensed health care professionals or other individuals authorized to administer the countermeasure under state law are covered by Section 304. In addition, any official, agent, or employee of any of these entities is also covered.

Q.10. Are state and local health departments and their employees covered by Section 304?

A.10. State and local health departments that act as distributors of countermeasures or that are healthcare entities under whose auspices countermeasures are administered are covered by Section 304. Their officials, agents, or employees are also covered for actions arising out of the administration of a countermeasure.

Q.11. Does Section 304 contain any limitations for covering these entities?

A.11. If a claim under Section 304 is based on an action or omission by a particular manufacturer, health care professional, or other person listed under item A.9 above, and that person fails to cooperate with the Government in the defense of the claim, the United States will not be liable for any damages resulting from that person’s act or omission. Also, if the United States makes a payment on a claim, and the payment is based (partly or wholly) on gross negligence, recklessness, illegal conduct, or willful misconduct by the manufacturer, health care professional, or other person listed under item A.9, or based on the person’s violation of a contract with the United States, the United States may recover that portion of the payment (with interest and litigation costs) from that person.

Q.12. What effect does Section 304 have upon federal or state workers’ compensation schemes?

A.12. Workers covered by state workers’ compensation statutes who suffer work-related injuries from the countermeasure may be barred from submitting a Section 304 claim if those state laws constitute an exclusive remedy. Federal employees who suffer such work-related injuries may only file claims pursuant to the Federal Employees’ Compensation Act.

Q.13. What legal standards apply to Section 304 claims?

A.13. In general, suits would be governed by state law as to liability and damages, except when provisions of the federal law provided otherwise. For example, a claimant must demonstrate that the injury or death attributable to the countermeasure was the result of a negligent or wrongful act or omission, regardless of the standard in the state where the act or omission occurred.

Q.14. Does the statute authorize payment for lost time from work or health care costs necessary for treating the injury?

A.14. If a claimant prevails on a Section 304 claim, damages would be determined according to state law, within any limits imposed by federal law. While loss of income and health care costs generally are recoverable, Section 304 does not establish a “no-fault” compensation program. See items A.2 and A.13. Individuals may wish to review their health insurance policies to determine whether they cover health-care costs for injuries attributable to administration of a smallpox countermeasure. For information on Section 304’s interaction with workers’ compensation claims, see item A.12.

Q.15. Are all persons working in a vaccination clinic covered by Section 304?

A.15. A vaccination clinic, as a healthcare entity under whose auspices a countermeasure is administered, is covered by Section 304 protections. Any official, employee, or agent of such a vaccination clinic would therefore also be covered by Section 304 protections for actions
Q.16. Will hospitals or other institutions who employ vaccinees but who do not operate as a clinic administering countermeasures be covered by Section 304 protections?

A.16. Generally, no. Only hospitals and institutions under whose auspices countermeasures are administered are covered by Section 304 protections.

Editor's Note: While the information available from the CDC is helpful in understanding the issues for health care providers involving the administration of the smallpox vaccines, undoubtedly there will be additional questions about the respective rights and responsibilities as the program gets underway. Jackson Lewis attorneys are available to assist health care providers in their response to the employment law challenges arising from the vaccination plans.

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