

Guidance for the Healthcare Community Concerning Section 304 of the Homeland Security Act

Manufacturers of smallpox vaccine and those healthcare entities under whose auspices the vaccine would be administered 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 relieve these liability concerns and therefore ensure that vaccine is available and can be administered in the event of an actual or potential public health emergency.

The following represents the Department of Health and Human Services' interpretation of Section 304, but is not an exhaustive review of Section 304's provisions in all contexts.

Overview

Under Section 304, no claim for liability for injury or death arising out of the administration of smallpox vaccine, other substances used to treat or prevent smallpox, or vaccinia immune globulin ("countermeasures") can be brought against entities or individuals who are covered by Section 304's protections. Instead these claims must be made against the United States.¹

Section 304 is triggered when the Secretary of Health and Human Services declares that administration of a countermeasure is advisable. The Secretary can make the declaration upon concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes the administration advisable, meaning that it can be made prior to the occurrence of a bioterrorist incident or public health emergency.

Among other things, the declaration will specify the category or categories of individuals it covers, and it will state how long it is in effect. It also will specify the countermeasures it covers, including vaccinia (smallpox) vaccine, cidofovir, and vaccinia immune globulin. To fully implement Section 304, the declaration also will provide further clarification of the statute's coverage.

Section 304 does not establish a compensation program that pays for any injury caused by administration of a smallpox countermeasure. In order to recover any payment pursuant to Section 304, an injured person must show that his/her injury is due to the negligence or wrongful act of an entity covered by Section 304's protections.

¹ Section 304 claims would be brought against the United States pursuant to the Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671, *et seq.*

Who Can File a Claim

Section 304 claims may be filed by:

- (1) injured individuals described in the declaration who, while the declaration is in effect, receive a declared countermeasure from a licensed health professional or other individual authorized to administer countermeasures under state law, or
- (2) injured individuals who did not receive a countermeasure, 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 did receive a countermeasure pursuant to the declaration.

Anyone in these categories who believes he or she has a claim attributable to injury or death due to a smallpox countermeasure must submit an administrative claim with an appropriate agency of the United States within two years of the accrual of that claim. If an administrative claim is denied, or if no action is taken on the claim within six months, the injured individual may file suit in federal court.

Who is Protected

The entities and individuals covered by Section 304's protections are:

- (1) manufacturers and distributors of countermeasures,
- (2) hospitals, clinics, and other healthcare entities under whose auspices the countermeasures are administered, and
- (3) licensed health care professionals or other individuals authorized to administer the countermeasures under state law ("qualified persons").

Officials, agents, and employees of any of these entities are also covered for claims arising out of the administration of a countermeasure that occur within the scope of employment.

Scope of Protection for State and Local Health Departments

State and local health departments that act as distributors of countermeasures or that are healthcare entities under whose auspices countermeasures are administered, as well as their officials, agents, and employees, are covered by Section 304.

Scope of Protection for Hospitals and Vaccine Clinics

Hospitals and other institutions that operate as vaccination clinics are covered by Section 304's protections for claims arising out of the administration of a countermeasure.

In addition, the Secretary's declaration may determine that hospitals that designate employees to receive smallpox countermeasures under a state's smallpox plan are considered to be participants in the program and thus are healthcare entities under whose auspices the countermeasure is administered. In these circumstances, we believe that hospitals or other institutions that employ these vaccinees but that do

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not operate as a clinic administering countermeasures would be covered by Section 304 protections for claims arising out of the administration of a countermeasure.

Scope of Protection for Healthcare Workers

“Qualified persons,” as noted above, 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 a qualified person administers the countermeasure.

Qualified persons are generally covered by Section 304’s protections for claims arising out of the administration of a countermeasure that occur within the scope of the qualified person’s employment. In addition, Section 304’s protections cover individuals who are officials, agents, and employees of entities listed in the Who is Protected section, above.

Limitations

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 Who Is Protected, 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 Who Is Protected, 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.

Workers’ Compensation

Workers’ compensation laws differ from state to state. If a work-related injury is covered by a particular state’s workers’ compensation law, that state’s law will determine whether the worker can sue any other person aside from the employer.

Workers may be barred from submitting a Section 304 claim if those state laws constitute an exclusive remedy (See attached diagram). If, on the other hand, the state law does allow a lawsuit against a party other than the worker’s employer, and the lawsuit is against an entity or individual listed in the Who is Protected section, the worker would have to bring the lawsuit pursuant to Section 304 and prove that a negligent or wrongful act occurred.

Federal employees who suffer work-related injuries may only file claims pursuant to the Federal Employees’ Compensation Act.

Section 304 does not bar workers’ compensation claims in the way it bars other suits. Other statutes, e.g., the Federal Tort Claims Act, that create similar remedies and that exclude other claims have been interpreted as not excluding workers’ compensation claims.

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Finally, workers' compensation claims themselves are not transformed by this legislation into separate claims covered by Section 304.

Attachment (1)