

is capable of determining without intervention by the user of the device whether defibrillation should be performed;

(iii) upon determining that defibrillation should be performed, is able to deliver an electrical shock to an individual; and

(iv) in the case of a defibrillator device that may be operated in either an automated or a manual mode, is set to operate in the automated mode.

(B)(i) The term “harm” includes physical, nonphysical, economic, and noneconomic losses.

(ii) The term “economic loss” means any pecuniary loss resulting from harm (including the loss of earnings or other benefits related to employment, medical expense loss, replacement services loss, loss due to death, burial costs, and loss of business or employment opportunities) to the extent recovery for such loss is allowed under applicable State law.

(iii) The term “noneconomic losses” means losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation and all other non-pecuniary losses of any kind or nature.

(July 1, 1944, ch. 373, title II, §248, as added Pub. L. 106-505, title IV, §404, Nov. 13, 2000, 114 Stat. 2338.)

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec. (e)(2)(A)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040, as amended, which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

PART C—SMALLPOX EMERGENCY PERSONNEL PROTECTION

§ 239. General provisions

(a) Definitions

For purposes of this part:

(1) Covered countermeasure

The term “covered countermeasure” means a covered countermeasure as specified in a Declaration made pursuant to section 233(p) of this title.

(2) Covered individual

The term “covered individual” means an individual—

(A) who is a health care worker, law enforcement officer, firefighter, security personnel, emergency medical personnel, other public safety personnel, or support personnel for such occupational specialties¹;

(B) who is or will be functioning in a role identified in a State, local, or Department of Health and Human Services smallpox emergency response plan (as defined in paragraph (7)) approved by the Secretary;

(C) who has volunteered and been selected to be a member of a smallpox emergency response plan described in subparagraph (B) prior to the time at which the Secretary publicly announces that an active case of smallpox has been identified either within or outside of the United States; and

(D) to whom a smallpox vaccine is administered pursuant to such approved plan during the effective period of the Declaration (including the portion of such period before April 30, 2003).

(3) Covered injury

The term “covered injury” means an injury, disability, illness, condition, or death (other than a minor injury such as minor scarring or minor local reaction) determined, pursuant to the procedures established under section 239a of this title, to have been sustained by an individual as the direct result of—

(A) administration to the individual of a covered countermeasure during the effective period of the Declaration; or

(B) accidental vaccinia inoculation of the individual in circumstances in which—

(i) the vaccinia is contracted during the effective period of the Declaration or within 30 days after the end of such period;

(ii) smallpox vaccine has not been administered to the individual; and

(iii) the individual has been in contact with an individual who is (or who was accidentally inoculated by) a covered individual.

(4) Declaration

The term “Declaration” means the Declaration Regarding Administration of Smallpox Countermeasures issued by the Secretary on January 24, 2003, and published in the Federal Register on January 28, 2003.

(5) Effective period of the Declaration

The term “effective period of the Declaration” means the effective period specified in the Declaration, unless extended by the Secretary.

(6) Eligible individual

The term “eligible individual” means an individual who is (as determined in accordance with section 239a of this title)—

(A) a covered individual who sustains a covered injury in the manner described in paragraph (3)(A); or

(B) an individual who sustains a covered injury in the manner described in paragraph (3)(B).

(7) Smallpox emergency response plan

The term “smallpox emergency response plan” or “plan” means a response plan detailing actions to be taken in preparation for a possible smallpox-related emergency during the period prior to the identification of an active case of smallpox either within or outside the United States.

(b) Voluntary program

The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to vaccinate individuals that is approved

¹ So in original. Probably should be “specialties”.

by the Secretary establishes procedures to ensure, consistent with the Declaration and any applicable guidelines of the Centers for Disease Control and Prevention, that—

(1) potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part;

(2) there is voluntary screening provided to potential participants that can identify health conditions relevant to contraindications; and

(3) there is appropriate post-inoculation medical surveillance that includes an evaluation of adverse health effects that may reasonably appear to be due to such vaccine and prompt referral of, or the provision of appropriate information to, any individual requiring health care as a result of such adverse health event.

(July 1, 1944, ch. 373, title II, § 261, as added Pub. L. 108–20, § 2, Apr. 30, 2003, 117 Stat. 638.)

§ 239a. Determination of eligibility and benefits

(a) In general

The Secretary shall establish procedures for determining, as applicable with respect to an individual—

(1) whether the individual is an eligible individual;

(2) whether an eligible individual has sustained a covered injury or injuries for which medical benefits or compensation may be available under sections 239c and 239d of this title, and the amount of such benefits or compensation; and

(3) whether the covered injury or injuries of an eligible individual caused the individual's death for purposes of benefits under section 239e of this title.

(b) Covered individuals

The Secretary may accept a certification, by a Federal, State, or local government entity or private health care entity participating in the administration of covered countermeasures under the Declaration, that an individual is a covered individual.

(c) Criteria for reimbursement

(1) Injuries specified in injury table

In any case where an injury or other adverse effect specified in the injury table established under section 239b of this title as a known effect of a vaccine manifests in an individual within the time period specified in such table, such injury or other effect shall be presumed to have resulted from administration of such vaccine.

(2) Other determinations

In making determinations other than those described in paragraph (1) as to the causation or severity of an injury, the Secretary shall employ a preponderance of the evidence standard and take into consideration all relevant medical and scientific evidence presented for consideration, and may obtain and consider the views of qualified medical experts.

(d) Deadline for filing request

The Secretary shall not consider any request for a benefit under this part with respect to an individual, unless—

(1) in the case of a request based on the administration of the vaccine to the individual, the individual files with the Secretary an initial request for benefits or compensation under this part not later than one year after the date of administration of the vaccine; or

(2) in the case of a request based on accidental vaccinia inoculation, the individual files with the Secretary an initial request for benefits or compensation under this part not later than two years after the date of the first symptom or manifestation of onset of the adverse effect.

(e) Structured settlements at Secretary's option

In any case in which there is a reasonable likelihood that compensation or payment under section 239c, 239d, or 239e(b) of this title will be required for a period in excess of one year from the date an individual is determined eligible for such compensation or payment, the Secretary shall have the discretion to make a lump-sum payment, purchase an annuity or medical insurance policy, or execute an appropriate structured settlement agreement, provided that such payment, annuity, policy, or agreement is actuarially determined to have a value equal to the present value of the projected total amount of benefits or compensation that the individual is eligible to receive under such section or sections.

(f) Review of determination

(1) Secretary's review authority

The Secretary may review a determination under this section at any time on the Secretary's own motion or on application, and may affirm, vacate, or modify such determination in any manner the Secretary deems appropriate. The Secretary shall develop a process by which an individual may file a request for reconsideration of any determination made by the Secretary under this section.

(2) Judicial and administrative review

No court of the United States, or of any State, District, territory or possession thereof, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this section. No officer or employee of the United States shall review any action by the Secretary under this section (unless the President specifically directs otherwise).

(July 1, 1944, ch. 373, title II, § 262, as added Pub. L. 108–20, § 2, Apr. 30, 2003, 117 Stat. 640.)

§ 239b. Smallpox vaccine injury table

(a)¹ Smallpox vaccine injury table

(1) Establishment required

The Secretary shall establish by interim final regulation a table identifying adverse effects (including injuries, disabilities, illnesses, conditions, and deaths) that shall be presumed

¹ So in original. No subsec. (b) has been enacted.