

(e) Definitions**(1) Perceived medical emergency**

For purposes of this section, the term “perceived medical emergency” means circumstances in which the behavior of an individual leads a reasonable person to believe that the individual is experiencing a life-threatening medical condition that requires an immediate medical response regarding the heart or other cardiopulmonary functioning of the individual.

(2) Other definitions

For purposes of this section:

(A) The term “automated external defibrillator device” means a defibrillator device that—

(i) is commercially distributed in accordance with the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.];

(ii) is capable of recognizing the presence or absence of ventricular fibrillation, and 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)—

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

(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 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 to result from the administration of (or exposure to) a smallpox vaccine, and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply.

(2) Amendments

The Secretary may by regulation amend the table established under paragraph (1). An amendment to the table takes effect on the date of the promulgation of the final rule that makes the amendment, and applies to all requests for benefits or compensation under this part that are filed on or after such date or are pending as of such date. In addition, the amendment applies retroactively to an individual who was not with respect to the injury involved an eligible individual under the table as in effect before the amendment but who with respect to such injury is an eligible individual under the table as amended. With respect to a request for benefits or compensation under this part by an individual who becomes an eligible individual as described in the preceding sentence, the Secretary may not provide such benefits or compensation unless the request (or amendment to a request, as applicable) is filed before the expiration of one year after the effective date of the amendment to the table in the case of an individual to whom the vaccine was administered and before the expiration of two years after such effective date in the case of a request based on accidental vaccinia inoculation.

(July 1, 1944, ch. 373, title II, § 263, as added Pub. L. 108-20, § 2, Apr. 30, 2003, 117 Stat. 641.)

§ 239c. Medical benefits

(a) In general

Subject to the succeeding provisions of this section, the Secretary shall make payment or reimbursement for medical items and services as reasonable and necessary to treat a covered injury of an eligible individual, including the services, appliances, and supplies prescribed or recommended by a qualified physician, which the Secretary considers likely to cure, give relief, reduce the degree or the period of disability, or aid in lessening the amount of monthly compensation.

(b) Benefits secondary to other coverage

Payment or reimbursement for services or benefits under subsection (a) of this section

shall be secondary to any obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer) under any other provision of law or contractual agreement, to pay for or provide such services or benefits.

(July 1, 1944, ch. 373, title II, § 264, as added Pub. L. 108-20, § 2, Apr. 30, 2003, 117 Stat. 641.)

§ 239d. Compensation for lost employment income

(a) In general

Subject to the succeeding provisions of this section, the Secretary shall provide compensation to an eligible individual for loss of employment income (based on such income at the time of injury) incurred as a result of a covered injury, at the rate specified in subsection (b) of this section.

(b) Amount of compensation

(1) In general

Compensation under subsection (a) of this section shall be at the rate of 66⅔ percent of the relevant pay period (weekly, monthly, or otherwise), except as provided in paragraph (2).

(2) Augmented compensation for dependents

If an eligible individual has one or more dependents, the basic compensation for loss of employment income as described in paragraph (1) shall be augmented at the rate of 8⅓ percent.

(3) Consideration of other programs

(A) In general

The Secretary may consider the provisions of sections 8114, 8115, and 8146a of title 5, and any implementing regulations, in determining the amount of payment under subsection (a) of this section and the circumstances under which such payments are reasonable and necessary.

(B) Minors

With respect to an eligible individual who is a minor, the Secretary may consider the provisions of section 8113 of title 5, and any implementing regulations, in determining the amount of payment under subsection (a) of this section and the circumstances under which such payments are reasonable and necessary.

(4) Treatment of self-employment income

For purposes of this section, the term “employment income” includes income from self-employment.

(c) Limitations

(1) Benefits secondary to other coverage

(A) In general

Any compensation under subsection (a) of this section shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability or retirement benefits.

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

(B) Relation to other obligations

Compensation under subsection (a) of this section shall not be made to an eligible individual to the extent that the total of amounts paid to the individual under such subsection and under the other obligations referred to in subparagraph (A) is an amount that exceeds the rate specified in subsection (b)(1) of this section. If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this paragraph, be deemed to be received over multiple years rather than received in a single year. The Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

(2) No benefits in case of death

No payment shall be made under subsection (a) of this section in compensation for loss of employment income subsequent to the receipt, by the survivor or survivors of an eligible individual, of benefits under section 239e of this title for death.

(3) Limit on total benefits**(A) In general**

Except as provided in subparagraph (B)—

(i) total compensation paid to an individual under subsection (a) of this section shall not exceed \$50,000 for any year; and

(ii) the lifetime total of such compensation for the individual may not exceed an amount equal to the amount authorized to be paid under section 239e of this title.

(B) Permanent and total disability

The limitation under subparagraph (A)(ii) does not apply in the case of an eligible individual who is determined to have a covered injury or injuries meeting the definition of disability in section 416(i) of this title.

(4) Waiting period**(A) In general**

Except as provided in subparagraph (B), an eligible individual shall not be provided compensation under this section for the first 5 work days of loss of employment income.

(B) Exception

Subparagraph (A) does not apply if the period of loss of employment income of an eligible individual is 10 or more work days.

(5) Termination of benefits

No payment shall be made under subsection (a) of this section in compensation for loss of employment income once the eligible individual involves¹ reaches the age of 65.

(d) Benefit in addition to medical benefits

A benefit under subsection (a) of this section shall be in addition to any amounts received by an eligible individual under section 239c of this title.

(July 1, 1944, ch. 373, title II, §265, as added Pub. L. 108–20, §2, Apr. 30, 2003, 117 Stat. 642.)

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

§ 239e. Payment for death**(a) Death benefit****(1) In general**

The Secretary shall pay, in the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, a death benefit in the amount determined under paragraph (2) to the survivor or survivors in the same manner as death benefits are paid pursuant to the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) with respect to an eligible deceased (except that in the case of an eligible individual who is a minor with no living parent, the legal guardian shall be considered the survivor in the place of the parent).

(2) Benefit amount**(A) In general**

The amount of the death benefit under paragraph (1) in a fiscal year shall equal the amount of the comparable benefit calculated under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) in such fiscal year, without regard to any reduction attributable to a limitation on appropriations, but subject to subparagraph (B).

(B) Reduction for payments for lost employment income

The amount of the benefit as determined under subparagraph (A) shall be reduced by the total amount of any benefits paid under section 239d of this title with respect to lost employment income.

(3) Limitations**(A) In general**

No benefit is payable under paragraph (1) with respect to the death of an eligible individual if—

(i) a disability benefit is paid with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.); or

(ii) a death benefit is paid or payable with respect to such individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.).

(B) Exception in the case of a limitation on appropriations for disability benefits under PSOB

In the event that disability benefits available to an eligible individual under the Public Safety Officers' Benefits Program under subpart 1 of part L of title I of the Omnibus Crime Control and Safe Streets Act of 1968 (42 U.S.C. 3796 et seq.) are reduced because of a limitation on appropriations, and such reduction would affect the amount that would

be payable under subparagraph (A) without regard to this subparagraph, benefits shall be available under paragraph (1) to the extent necessary to ensure that the survivor or survivors of such individual receives a total amount equal to the amount described in paragraph (2).

(b) Election in case of dependents

(1) In general

In the case of an eligible individual whose death is determined to have resulted from a covered injury or injuries, if the individual had one or more dependents under the age of 18, the legal guardian of the dependents may, in lieu of the death benefit under subsection (a) of this section, elect to receive on behalf of the aggregate of such dependents payments in accordance with this subsection. An election under the preceding sentence is effective in lieu of a request under subsection (a) of this section by an individual who is not the legal guardian of such dependents.

(2) Amount of payments

Payments under paragraph (1) with respect to an eligible individual described in such paragraph shall be made as if such individual were an eligible individual to whom compensation would be paid under subsection (a) of section 239d of this title, with the rate augmented in accordance with subsection (b)(2) of such section and with such individual considered to be an eligible individual described in subsection (c)(3)(B) of such section.

(3) Limitations

(A) Age of dependents

No payments may be made under paragraph (1) once the youngest of the dependents involved reaches the age of 18.

(B) Benefits secondary to other coverage

(i) In general

Any payment under paragraph (1) shall be secondary to the obligation of the United States or any third party (including any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay compensation for loss of employment income or to provide disability benefits, retirement benefits, life insurance benefits on behalf of dependents under the age of 18, or death benefits.

(ii) Relation to other obligations

Payments under paragraph (1) shall not be made to with respect to¹ an eligible individual to the extent that the total of amounts paid with respect to the individual under such paragraph and under the other obligations referred to in clause (i) is an amount that exceeds the rate of payment that applies under paragraph (2). If under any such other obligation a lump-sum payment is made, such payment shall, for purposes of this subparagraph, be deemed to be received over multiple years rather than received in a single year. The

Secretary may, in the discretion of the Secretary, determine how to apportion such payment over multiple years.

(c) Benefit in addition to medical benefits

A benefit under subsection (a) or (b) of this section shall be in addition to any amounts received by an eligible individual under section 239c of this title.

(July 1, 1944, ch. 373, title II, §266, as added Pub. L. 108-20, §2, Apr. 30, 2003, 117 Stat. 643.)

REFERENCES IN TEXT

The Omnibus Crime Control and Safe Streets Act of 1968, referred to in subsec. (a)(1), (2)(A), (3), is Pub. L. 90-351, June 19, 1968, 82 Stat. 197, as amended. Subpart 1 of part L of title I of the Act is classified generally to part A (§3796 et seq.) of subchapter XII of chapter 46 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 3711 of this title and Tables.

§ 239f. Administration

(a) Administration by agreement with other agency or agencies

The Secretary may administer any or all of the provisions of this part through Memorandum of Agreement with the head of any appropriate Federal agency.

(b) Regulations

The head of the agency administering this part or provisions thereof (including any agency head administering such Act¹ or provisions through a Memorandum of Agreement under subsection (a) of this section) may promulgate such implementing regulations as may be found necessary and appropriate. Initial implementing regulations may be interim final regulations.

(July 1, 1944, ch. 373, title II, §267, as added Pub. L. 108-20, §2, Apr. 30, 2003, 117 Stat. 645.)

§ 239g. Authorization of appropriations

For the purpose of carrying out this part, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2003 through 2007, to remain available until expended, including administrative costs and costs of provision and payment of benefits. The Secretary's payment of any benefit under section 239c, 239d, or 239e of this title shall be subject to the availability of appropriations under this section.

(July 1, 1944, ch. 373, title II, §268, as added Pub. L. 108-20, §2, Apr. 30, 2003, 117 Stat. 645.)

§ 239h. Relationship to other laws

Except as explicitly provided herein, nothing in this part shall be construed to override or limit any rights an individual may have to seek compensation, benefits, or redress under any other provision of Federal or State law.

(July 1, 1944, ch. 373, title II, §269, as added Pub. L. 108-20, §2, Apr. 30, 2003, 117 Stat. 645.)

¹ So in original.

¹ So in original. Probably should be "part".

SUBCHAPTER II—GENERAL POWERS AND DUTIES

PART A—RESEARCH AND INVESTIGATIONS

§ 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to—

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections 2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral

research, substances and living organisms. Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains—

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on the basis of available