

agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

Functions of Federal Works Agency and of all agencies thereof, together with functions of Federal Works Administrator transferred to Administrator of General Services by section 103(a) of act June 30, 1949. Both Federal Works Agency and office of Federal Works Administrator abolished by section 103(b) of that act. See Historical and Revision Notes under section 303(b) of Title 40, Public Buildings, Property, and Works. Section 303(b) of Title 40 was amended generally by Pub. L. 109-313, §2(a)(1), Oct. 6, 2006, 120 Stat. 1734, and, as so amended, no longer relates to the Federal Works Agency and Commissioner of Public Buildings. See 2006 Amendment note under section 303 of Title 40.

EFFECTIVE DATE OF TRANSFER OF FUNCTIONS

Transfer of functions by act June 30, 1949, effective July 1, 1949, see section 605, formerly section 505, of act June 30, 1949, ch. 288, 63 Stat. 403; renumbered by act Sept. 5, 1950, ch. 849, §6(a), (b), 64 Stat. 583.

§ 233. Civil actions or proceedings against commissioned officers or employees

(a) Exclusiveness of remedy

The remedy against the United States provided by sections 1346(b) and 2672 of title 28, or by alternative benefits provided by the United States where the availability of such benefits precludes a remedy under section 1346(b) of title 28, for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigation, by any commissioned officer or employee of the Public Health Service while acting within the scope of his office or employment, shall be exclusive of any other civil action or proceeding by reason of the same subject-matter against the officer or employee (or his estate) whose act or omission gave rise to the claim.

(b) Attorney General to defend action or proceeding; delivery of process to designated official; furnishing of copies of pleading and process to United States attorney, Attorney General, and Secretary

The Attorney General shall defend any civil action or proceeding brought in any court against any person referred to in subsection (a) of this section (or his estate) for any such damage or injury. Any such person against whom such civil action or proceeding is brought shall deliver within such time after date of service or knowledge of service as determined by the Attorney General, all process served upon him or an attested true copy thereof to his immediate superior or to whomever was designated by the Secretary to receive such papers and such person shall promptly furnish copies of the pleading and process therein to the United States attorney for the district embracing the place wherein the proceeding is brought, to the Attorney General, and to the Secretary.

(c) Removal to United States district court; procedure; proceeding upon removal deemed a tort action against United States; hearing on motion to remand to determine availability of remedy against United States; remand to State court or dismissal

Upon a certification by the Attorney General that the defendant was acting in the scope of his employment at the time of the incident out of which the suit arose, any such civil action or proceeding commenced in a State court shall be removed without bond at any time before trial by the Attorney General to the district court of the United States of the district and division embracing the place wherein it is pending and the proceeding deemed a tort action brought against the United States under the provisions of title 28 and all references thereto. Should a United States district court determine on a hearing on a motion to remand held before a trial on the merit that the case so removed is one in which a remedy by suit within the meaning of subsection (a) of this section is not available against the United States, the case shall be remanded to the State Court: *Provided*, That where such a remedy is precluded because of the availability of a remedy through proceedings for compensation or other benefits from the United States as provided by any other law, the case shall be dismissed, but in the event the running of any limitation of time for commencing, or filing an application or claim in, such proceedings for compensation or other benefits shall be deemed to have been suspended during the pendency of the civil action or proceeding under this section.

(d) Compromise or settlement of claim by Attorney General

The Attorney General may compromise or settle any claim asserted in such civil action or proceeding in the manner provided in section 2677 of title 28 and with the same effect.

(e) Assault or battery

For purposes of this section, the provisions of section 2680(h) of title 28 shall not apply to assault or battery arising out of negligence in the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations.

(f) Authority of Secretary or designee to hold harmless or provide liability insurance for assigned or detailed employees

The Secretary or his designee may, to the extent that he deems appropriate, hold harmless or provide liability insurance for any officer or employee of the Public Health Service for damage for personal injury, including death, negligently caused by such officer or employee while acting within the scope of his office or employment and as a result of the performance of medical, surgical, dental, or related functions, including the conduct of clinical studies or investigations, if such employee is assigned to a foreign country or detailed to a State or political subdivision thereof or to a non-profit institution, and if the circumstances are such as are likely to preclude the remedies of third persons against the United States described in section 2679(b) of title 28, for such damage or injury.

(g) Exclusivity of remedy against United States for entities deemed Public Health Service employees; coverage for services furnished to individuals other than center patients; application process; subrogation of medical malpractice claims; applicable period; entity and contractor defined

(1)(A) For purposes of this section and subject to the approval by the Secretary of an application under subparagraph (D), an entity described in paragraph (4), and any officer, governing board member, or employee of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, governing board member, employee, or contractor (subject to paragraph (5)) of such an entity who is deemed to be an employee of the Public Health Service pursuant to this paragraph shall be exclusive of any other civil action or proceeding to the same extent as the remedy against the United States is exclusive pursuant to subsection (a).

(B) The deeming of any entity or officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section shall apply with respect to services provided—

(i) to all patients of the entity, and

(ii) subject to subparagraph (C), to individuals who are not patients of the entity.

(C) Subparagraph (B)(ii) applies to services provided to individuals who are not patients of an entity if the Secretary determines, after reviewing an application submitted under subparagraph (D), that the provision of the services to such individuals—

(i) benefits patients of the entity and general populations that could be served by the entity through community-wide intervention efforts within the communities served by such entity;

(ii) facilitates the provision of services to patients of the entity; or

(iii) are otherwise required under an employment contract (or similar arrangement) between the entity and an officer, governing board member, employee, or contractor of the entity.

(D) The Secretary may not under subparagraph (A) deem an entity or an officer, governing board member, employee, or contractor of the entity to be an employee of the Public Health Service for purposes of this section, and may not apply such deeming to services described in subparagraph (B)(ii), unless the entity has submitted an application for such deeming to the Secretary in such form and such manner as the Secretary shall prescribe. The application shall contain detailed information, along with supporting documentation, to verify that the entity, and the officer, governing board member, employee, or contractor of the entity, as the case may be, meets the requirements of subpara-

graphs (B) and (C) of this paragraph and that the entity meets the requirements of paragraphs (1) through (4) of subsection (h).

(E) The Secretary shall make a determination of whether an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section within 30 days after the receipt of an application under subparagraph (D). The determination of the Secretary that an entity or an officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section shall apply for the period specified by the Secretary under subparagraph (A).

(F) Once the Secretary makes a determination that an entity or an officer, governing board member, employee, or contractor of an entity is deemed to be an employee of the Public Health Service for purposes of this section, the determination shall be final and binding upon the Secretary and the Attorney General and other parties to any civil action or proceeding. Except as provided in subsection (i), the Secretary and the Attorney General may not determine that the provision of services which are the subject of such a determination are not covered under this section.

(G) In the case of an entity described in paragraph (4) that has not submitted an application under subparagraph (D):

(i) The Secretary may not consider the entity in making estimates under subsection (k)(1).

(ii) This section does not affect any authority of the entity to purchase medical malpractice liability insurance coverage with Federal funds provided to the entity under section 254b, 254b, or 256a of this title.¹

(H) In the case of an entity described in paragraph (4) for which an application under subparagraph (D) is in effect, the entity may, through notifying the Secretary in writing, elect to terminate the applicability of this subsection to the entity. With respect to such election by the entity:

(i) The election is effective upon the expiration of the 30-day period beginning on the date on which the entity submits such notification.

(ii) Upon taking effect, the election terminates the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor of the entity.

(iii) Upon the effective date for the election, clauses (i) and (ii) of subparagraph (G) apply to the entity to the same extent and in the same manner as such clauses apply to an entity that has not submitted an application under subparagraph (D).

(iv) If after making the election the entity submits an application under subparagraph (D), the election does not preclude the Secretary from approving the application (²and thereby restoring the applicability of this subsection to the entity and each officer, governing board member, employee, and contractor

¹ See References in Text notes below.

² So in original. There is no closing parenthesis.

of the entity, subject to the provisions of this subsection and the subsequent provisions of this section.

(2) If, with respect to an entity or person deemed to be an employee for purposes of paragraph (1), a cause of action is instituted against the United States pursuant to this section, any claim of the entity or person for benefits under an insurance policy with respect to medical malpractice relating to such cause of action shall be subrogated to the United States.

(3) This subsection shall apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1993.

(4) An entity described in this paragraph is a public or non-profit private entity receiving Federal funds under section 254b of this title.

(5) For purposes of paragraph (1), an individual may be considered a contractor of an entity described in paragraph (4) only if—

(A) the individual normally performs on average at least 32½ hours of service per week for the entity for the period of the contract; or

(B) in the case of an individual who normally performs an average of less than 32½ hours of services per week for the entity for the period of the contract, the individual is a licensed or certified provider of services in the fields of family practice, general internal medicine, general pediatrics, or obstetrics and gynecology.

(h) Qualifications for designation as Public Health Service employee

The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—

(1) has implemented appropriate policies and procedures to reduce the risk of malpractice and the risk of lawsuits arising out of any health or health-related functions performed by the entity;

(2) has reviewed and verified the professional credentials, references, claims history, fitness, professional review organization findings, and license status of its physicians and other licensed or certified health care practitioners, and, where necessary, has obtained the permission from these individuals to gain access to this information;

(3) has no history of claims having been filed against the United States as a result of the application of this section to the entity or its officers, employees, or contractors as provided for under this section, or, if such a history exists, has fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

(4) will fully cooperate with the Attorney General in providing information relating to an estimate described under subsection (k).

(i) Authority of Attorney General to exclude health care professionals from coverage

(1) Notwithstanding subsection (g)(1), the Attorney General, in consultation with the Secretary, may on the record determine, after notice and opportunity for a full and fair hearing, that an individual physician or other licensed or

certified health care practitioner who is an officer, employee, or contractor of an entity described in subsection (g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of this section, if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss because such individual—

(A) does not comply with the policies and procedures that the entity has implemented pursuant to subsection (h)(1);

(B) has a history of claims filed against him or her as provided for under this section that is outside the norm for licensed or certified health care practitioners within the same specialty;

(C) refused to reasonably cooperate with the Attorney General in defending against any such claim;

(D) provided false information relevant to the individual's performance of his or her duties to the Secretary, the Attorney General, or an applicant for or recipient of funds under this chapter; or

(E) was the subject of disciplinary action taken by a State medical licensing authority or a State or national professional society.

(2) A final determination by the Attorney General under this subsection that an individual physician or other licensed or certified health care professional shall not be deemed to be an employee of the Public Health Service shall be effective upon receipt by the entity employing such individual of notice of such determination, and shall apply only to acts or omissions occurring after the date such notice is received.

(j) Remedy for denial of hospital admitting privileges to certain health care providers

In the case of a health care provider who is an officer, employee, or contractor of an entity described in subsection (g)(4), section 254h(e) of this title shall apply with respect to the provider to the same extent and in the same manner as such section applies to any member of the National Health Service Corps.

(k) Estimate of annual claims by Attorney General; criteria; establishment of fund; transfer of funds to Treasury accounts

(1)(A) For each fiscal year, the Attorney General, in consultation with the Secretary, shall estimate by the beginning of the year the amount of all claims which are expected to arise under this section (together with related fees and expenses of witnesses) for which payment is expected to be made in accordance with section 1346 and chapter 171 of title 28 from the acts or omissions, during the calendar year that begins during that fiscal year, of entities described in subsection (g)(4) and of officers, employees, or contractors (subject to subsection (g)(5)) of such entities.

(B) The estimate under subparagraph (A) shall take into account—

(i) the value and frequency of all claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by entities described in subsection (g)(4) or by officers, employees, or contractors (subject to

subsection (g)(5) of such entities who are deemed to be employees of the Public Health Service under subsection (g)(1) that, during the preceding 5-year period, are filed under this section or, with respect to years occurring before this subsection takes effect, are filed against persons other than the United States,

(ii) the amounts paid during that 5-year period on all claims described in clause (i), regardless of when such claims were filed, adjusted to reflect payments which would not be permitted under section 1346 and chapter 171 of title 28, and

(iii) amounts in the fund established under paragraph (2) but unspent from prior fiscal years.

(2) Subject to appropriations, for each fiscal year, the Secretary shall establish a fund of an amount equal to the amount estimated under paragraph (1) that is attributable to entities receiving funds under each of the grant programs described in paragraph (4) of subsection (g), but not to exceed a total of \$10,000,000 for each such fiscal year. Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 254b, 254b and 256a of this title.¹

(3) In order for payments to be made for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of entities described in subsection (g)(4) and of officers, governing board member,³ employees, or contractors (subject to subsection (g)(5)) of such entities, the total amount contained within the fund established by the Secretary under paragraph (2) for a fiscal year shall be transferred not later than the December 31 that occurs during the fiscal year to the appropriate accounts in the Treasury.

(l) Timely response to filing of action or proceeding

(1) If a civil action or proceeding is filed in a State court against any entity described in subsection (g)(4) or any officer, governing board member, employee, or any contractor of such an entity for damages described in subsection (a), the Attorney General, within 15 days after being notified of such filing, shall make an appearance in such court and advise such court as to whether the Secretary has determined under subsections (g) and (h), that such entity, officer, governing board member, employee, or contractor of the entity is deemed to be an employee of the Public Health Service for purposes of this section with respect to the actions or omissions that are the subject of such civil action or proceeding. Such advice shall be deemed to satisfy the provisions of subsection (c) that the Attorney General certify that an entity, officer, governing board member, employee, or contractor of the entity was acting within the scope of their employment or responsibility.

(2) If the Attorney General fails to appear in State court within the time period prescribed under paragraph (1), upon petition of any entity or officer, governing board member, employee, or contractor of the entity named, the civil ac-

tion or proceeding shall be removed to the appropriate United States district court. The civil action or proceeding shall be stayed in such court until such court conducts a hearing, and makes a determination, as to the appropriate forum or procedure for the assertion of the claim for damages described in subsection (a) and issues an order consistent with such determination.

(m) Application of coverage to managed care plans

(1) An entity or officer, governing board member, employee, or contractor of an entity described in subsection (g)(1) shall, for purposes of this section, be deemed to be an employee of the Public Health Service with respect to services provided to individuals who are enrollees of a managed care plan if the entity contracts with such managed care plan for the provision of services.

(2) Each managed care plan which enters into a contract with an entity described in subsection (g)(4) shall deem the entity and any officer, governing board member, employee, or contractor of the entity as meeting whatever malpractice coverage requirements such plan may require of contracting providers for a calendar year if such entity or officer, governing board member, employee, or contractor of the entity has been deemed to be an employee of the Public Health Service for purposes of this section for such calendar year. Any plan which is found by the Secretary on the record, after notice and an opportunity for a full and fair hearing, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under titles XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.].

(3) For purposes of this subsection, the term "managed care plan" shall mean health maintenance organizations and similar entities that contract at-risk with payors for the provision of health services or plan enrollees and which contract with providers (such as entities described in subsection (g)(4)) for the delivery of such services to plan enrollees.

(n) Report on risk exposure of covered entities

(1) Not later than one year after December 26, 1995, the Comptroller General of the United States shall submit to the Congress a report on the following:

(A) The medical malpractice liability claims experience of entities that have been deemed to be employees for purposes of this section.

(B) The risk exposure of such entities.

(C) The value of private sector risk-management services, and the value of risk-management services and procedures required as a condition of receiving a grant under section 254b, 254b, or 256a of this title.¹

(D) A comparison of the costs and the benefits to taxpayers of maintaining medical malpractice liability coverage for such entities pursuant to this section, taking into account—

(i) a comparison of the costs of premiums paid by such entities for private medical malpractice liability insurance with the cost of coverage pursuant to this section; and

³ So in original. Probably should be "members."

(ii) an analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of such entities.

(2) The report under paragraph (1) shall include the following:

(A) A comparison of—

(i) an estimate of the aggregate amounts that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) would have directly or indirectly paid in premiums to obtain medical malpractice liability insurance coverage if this section were not in effect; with

(ii) the aggregate amounts by which the grants received by such entities under this chapter were reduced pursuant to subsection (k)(2).

(B) A comparison of—

(i) an estimate of the amount of privately offered such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) purchased during the three-year period beginning on January 1, 1993; with

(ii) an estimate of the amount of such insurance that such entities (together with the officers, governing board members, employees, and contractors of such entities who have been deemed to be employees for purposes of this section) will purchase after December 26, 1995.

(C) An estimate of the medical malpractice liability loss history of such entities for the 10-year period preceding October 1, 1996, including but not limited to the following:

(i) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by the Federal Government pursuant to deeming entities as employees for purposes of this section.

(ii) Claims that have been paid and that are estimated to be paid, and legal expenses to handle such claims that have been paid and that are estimated to be paid, by private medical malpractice liability insurance.

(D) An analysis of whether the cost of premiums for private medical malpractice liability insurance coverage is consistent with the liability claims experience of entities that have been deemed as employees for purposes of this section.

(3) In preparing the report under paragraph (1), the Comptroller General of the United States shall consult with public and private entities with expertise on the matters with which the report is concerned.

(o) Volunteer services provided by health professionals at free clinics

(1) For purposes of this section, a free clinic health professional shall in providing a qualifying health service to an individual, or an officer,

governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (6)(D). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a free clinic health professional if the following conditions are met:

(A) The service is provided to the individual at a free clinic, or through offsite programs or events carried out by the free clinic.

(B) The free clinic is sponsoring the health care practitioner pursuant to paragraph (5)(C).

(C) The service is a qualifying health service (as defined in paragraph (4)).

(D) Neither the health care practitioner nor the free clinic receives any compensation for the service from the individual or from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program). With respect to compliance with such condition:

(i) The health care practitioner may receive repayment from the free clinic for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual.

(ii) The free clinic may accept voluntary donations for the provision of the service by the health care practitioner to the individual.

(E) Before the service is provided, the health care practitioner or the free clinic provides written notice to the individual of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection (or in the case of an emergency, the written notice is provided to the individual as soon after the emergency as is practicable). If the individual is a minor or is otherwise legally incompetent, the condition under this subparagraph is that the written notice be provided to a legal guardian or other person with legal responsibility for the care of the individual.

(F) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable law regarding the provision of the service.

(3)(A) For purposes of this subsection, the term “free clinic” means a health care facility operated by a nonprofit private entity meeting the following requirements:

(i) The entity does not, in providing health services through the facility, accept reimbursement from any third-party payor (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

(ii) The entity, in providing health services through the facility, either does not impose charges on the individuals to whom the services are provided, or imposes a charge according to the ability of the individual involved to pay the charge.

(iii) The entity is licensed or certified in accordance with applicable law regarding the provision of health services.

(B) With respect to compliance with the conditions under subparagraph (A), the entity involved may accept voluntary donations for the provision of services.

(4) For purposes of this subsection, the term “qualifying health service” means any medical assistance required or authorized to be provided in the program under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.], without regard to whether the medical assistance is included in the plan submitted under such program by the State in which the health care practitioner involved provides the medical assistance. References in the preceding sentence to such program shall as applicable be considered to be references to any successor to such program.

(5) Subsection (g) (other than paragraphs (3) through (5)) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (6) and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) This subsection may not be construed as deeming any free clinic to be an employee of the Public Health Service for purposes of this section.

(C) With respect to a free clinic, a health care practitioner is not a free clinic health professional unless the free clinic sponsors the health care practitioner. For purposes of this subsection, the free clinic shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the free clinic submits to the Secretary an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(D) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a free clinic health professional, this subsection applies to the health care practitioner (with respect to the free clinic sponsoring the health care practitioner pursuant to subparagraph (C)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(E) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(6)(A) For purposes of making payments for judgments against the United States (together with related fees and expenses of witnesses) pur-

suant to this section arising from the acts or omissions of free clinic health professionals, there is authorized to be appropriated \$10,000,000 for each fiscal year.

(B) The Secretary shall establish a fund for purposes of this subsection. Each fiscal year amounts appropriated under subparagraph (A) shall be deposited in such fund.

(C) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of free clinic health professionals, will be paid pursuant to this section during the calendar year that begins in the following fiscal year. Subsection (k)(1)(B) applies to the estimate under the preceding sentence regarding free clinic health professionals to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(D) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subparagraph (B) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (C) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(7)(A) This subsection takes effect on the date of the enactment of the first appropriations Act that makes an appropriation under paragraph (6)(A), except as provided in subparagraph (B)(i).

(B)(i) Effective on August 21, 1996—

(I) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (5)(C); and

(II) reports under paragraph (6)(C) may be submitted to the Congress.

(ii) For the first fiscal year for which an appropriation is made under subparagraph (A) of paragraph (6), if an estimate under subparagraph (C) of such paragraph has not been made for the calendar year beginning in such fiscal year, the transfer under subparagraph (D) of such paragraph shall be made notwithstanding the lack of the estimate, and the transfer shall be made in an amount equal to the amount of such appropriation.

(p) Administration of smallpox countermeasures by health professionals

(1) In general

For purposes of this section, and subject to other provisions of this subsection, a covered person shall be deemed to be an employee of the Public Health Service with respect to liability arising out of administration of a covered countermeasure against smallpox to an individual during the effective period of a declaration by the Secretary under paragraph (2)(A).

(2) Declaration by Secretary concerning countermeasure against smallpox

(A) Authority to issue declaration

(i) In general

The Secretary may issue a declaration, pursuant to this paragraph, concluding that an actual or potential bioterrorist incident or other actual or potential public health emergency makes advisable the administration of a covered countermeasure to a category or categories of individuals.

(ii) Covered countermeasure

The Secretary shall specify in such declaration the substance or substances that shall be considered covered countermeasures (as defined in paragraph (7)(A)) for purposes of administration to individuals during the effective period of the declaration.

(iii) Effective period

The Secretary shall specify in such declaration the beginning and ending dates of the effective period of the declaration, and may subsequently amend such declaration to shorten or extend such effective period, provided that the new closing date is after the date when the declaration is amended.

(iv) Publication

The Secretary shall promptly publish each such declaration and amendment in the Federal Register.

(B) Liability of United States only for administrations within scope of declaration

Except as provided in paragraph (5)(B)(ii), 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 only if—

(i) the countermeasure was administered by a qualified person, for a purpose stated in paragraph (7)(A)(i), and during the effective period of a declaration by the Secretary under subparagraph (A) with respect to such countermeasure; and

(ii)(I) the individual was within a category of individuals covered by the declaration; or

(II) the qualified person administering the countermeasure had reasonable grounds to believe that such individual was within such category.

(C) Presumption of administration within scope of declaration in case of accidental vaccinia inoculation

(i) In general

If vaccinia vaccine is a covered countermeasure specified in a declaration under subparagraph (A), and an individual to whom the vaccinia vaccine is not administered contracts vaccinia, then, under the circumstances specified in clause (ii), the individual—

(I) shall be rebuttably presumed to have contracted vaccinia from an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B); and

(II) shall (unless such presumption is rebutted) be deemed for purposes of this subsection to be an individual to whom a covered countermeasure was administered by a qualified person in accordance with the terms of such declaration and as described by subparagraph (B).

(ii) Circumstances in which presumption applies

The presumption and deeming stated in clause (i) shall apply if—

(I) the individual contracts vaccinia during the effective period of a declaration under subparagraph (A) or by the date 30 days after the close of such period; or

(II) the individual has resided with, or has had contact with, an individual to whom such vaccine was administered as provided by clauses (i) and (ii) of subparagraph (B) and contracts vaccinia after such date.

(D) Acts and omissions deemed to be within scope of employment

(i) In general

In the case of a claim arising out of alleged transmission of vaccinia from an individual described in clause (ii), acts or omissions by such individual shall be deemed to have been taken within the scope of such individual's office or employment for purposes of—

(I) subsection (a); and

(II) section 1346(b) and chapter 171 of title 28.

(ii) Individuals to whom deeming applies

An individual is described by this clause if—

(I) vaccinia vaccine was administered to such individual as provided by subparagraph (B); and

(II) such individual was within a category of individuals covered by a declaration under subparagraph (A)(i).

(3) Exhaustion; exclusivity; offset

(A) Exhaustion

(i) In general

A person may not bring a claim under this subsection unless such person has exhausted such remedies as are available under part C of this subchapter, except that if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of such part within 240 days after such request was filed, the individual may seek any remedy that may be available under this section.

(ii) Tolling of statute of limitations

The time limit for filing a claim under this subsection, or for filing an action based on such claim, shall be tolled during the pendency of a request for benefits or compensation under part C of this subchapter.

(iii) Construction

This subsection shall not be construed as superseding or otherwise affecting the ap-

plication of a requirement, under chapter 171 of title 28, to exhaust administrative remedies.

(B) Exclusivity

The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses, except for a proceeding under part C of this subchapter.

(C) Offset

The value of all compensation and benefits provided under part C of this subchapter for an incident or series of incidents shall be offset against the amount of an award, compromise, or settlement of money damages in a claim or suit under this subsection based on the same incident or series of incidents.

(4) Certification of action by Attorney General

Subsection (c) applies to actions under this subsection, subject to the following provisions:

(A) Nature of certification

The certification by the Attorney General that is the basis for deeming an action or proceeding to be against the United States, and for removing an action or proceeding from a State court, is a certification that the action or proceeding is against a covered person and is based upon a claim alleging personal injury or death arising out of the administration of a covered countermeasure.

(B) Certification of Attorney General conclusive

The certification of the Attorney General of the facts specified in subparagraph (A) shall conclusively establish such facts for purposes of jurisdiction pursuant to this subsection.

(5) Covered person to cooperate with United States

(A) In general

A covered person shall cooperate with the United States in the processing and defense of a claim or action under this subsection based upon alleged acts or omissions of such person.

(B) Consequences of failure to cooperate

Upon the motion of the United States or any other party and upon finding that such person has failed to so cooperate—

(i) the court shall substitute such person as the party defendant in place of the United States and, upon motion, shall remand any such suit to the court in which it was instituted if it appears that the court lacks subject matter jurisdiction;

(ii) the United States shall not be liable based on the acts or omissions of such person; and

(iii) the Attorney General shall not be obligated to defend such action.

(6) Recourse against covered person in case of gross misconduct or contract violation

(A) In general

Should payment be made by the United States to any claimant bringing a claim

under this subsection, either by way of administrative determination, settlement, or court judgment, the United States shall have, notwithstanding any provision of State law, the right to recover for that portion of the damages so awarded or paid, as well as interest and any costs of litigation, resulting from the failure of any covered person to carry out any obligation or responsibility assumed by such person under a contract with the United States or from any grossly negligent, reckless, or illegal conduct or willful misconduct on the part of such person.

(B) Venue

The United States may maintain an action under this paragraph against such person in the district court of the United States in which such person resides or has its principal place of business.

(7) Definitions

As used in this subsection, terms have the following meanings:

(A) Covered countermeasure

The term “covered countermeasure” or “covered countermeasure against smallpox”, means a substance that is—

(i)(I) used to prevent or treat smallpox (including the vaccinia or another vaccine); or

(II) used to control or treat the adverse effects of vaccinia inoculation or of administration of another covered countermeasure; and

(ii) specified in a declaration under paragraph (2).

(B) Covered person

The term “covered person”, when used with respect to the administration of a covered countermeasure, means a person who is—

(i) a manufacturer or distributor of such countermeasure;

(ii) a health care entity under whose auspices—

(I) such countermeasure was administered;

(II) a determination was made as to whether, or under what circumstances, an individual should receive a covered countermeasure;

(III) the immediate site of administration on the body of a covered countermeasure was monitored, managed, or cared for; or

(IV) an evaluation was made of whether the administration of a countermeasure was effective;

(iii) a qualified person who administered such countermeasure;

(iv) a State, a political subdivision of a State, or an agency or official of a State or of such a political subdivision, if such State, subdivision, agency, or official has established requirements, provided policy guidance, supplied technical or scientific advice or assistance, or otherwise supervised or administered a program with re-

spect to administration of such countermeasures;

(v) in the case of a claim arising out of alleged transmission of vaccinia from an individual—

(I) the individual who allegedly transmitted the vaccinia, if vaccinia vaccine was administered to such individual as provided by paragraph (2)(B) and such individual was within a category of individuals covered by a declaration under paragraph (2)(A)(i); or

(II) an entity that employs an individual described by clause (I)⁴ or where such individual has privileges or is otherwise authorized to provide health care;

(vi) an official, agent, or employee of a person described in clause (i), (ii), (iii), or (iv);

(vii) a contractor of, or a volunteer working for, a person described in clause (i), (ii), or (iv), if the contractor or volunteer performs a function for which a person described in clause (i), (ii), or (iv) is a covered person; or

(viii) an individual who has privileges or is otherwise authorized to provide health care under the auspices of an entity described in clause (ii) or (v)(II).

(C) Qualified person

The term “qualified person”, when used with respect to the administration of a covered countermeasure, means a licensed health professional or other individual who—

(i) is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered; or

(ii) is otherwise authorized by the Secretary to administer such countermeasure.

(D) Arising out of administration of a covered countermeasure

The term “arising out of administration of a covered countermeasure”, when used with respect to a claim or liability, includes a claim or liability arising out of—

(i) determining whether, or under what conditions, an individual should receive a covered countermeasure;

(ii) obtaining informed consent of an individual to the administration of a covered countermeasure;

(iii) monitoring, management, or care of an immediate site of administration on the body of a covered countermeasure, or evaluation of whether the administration of the countermeasure has been effective; or

(iv) transmission of vaccinia virus by an individual to whom vaccinia vaccine was administered as provided by paragraph (2)(B).

(q) Health professional volunteers at public or non-profit private entities

(1) For purposes of this section, a health professional volunteer at a deemed entity described

in subsection (g)(4) shall, in providing a health professional service eligible for funding under section 254b of this title to an individual, be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under paragraph (4)(C). The preceding sentence is subject to the provisions of this subsection.

(2) In providing a health service to an individual, a health care practitioner shall for purposes of this subsection be considered to be a health professional volunteer at an entity described in subsection (g)(4) if the following conditions are met:

(A) The service is provided to the individual at the facilities of an entity described in subsection (g)(4), or through offsite programs or events carried out by the entity.

(B) The entity is sponsoring the health care practitioner pursuant to paragraph (3)(B).

(C) The health care practitioner does not receive any compensation for the service from the individual, the entity described in subsection (g)(4), or any third-party payer (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program), except that the health care practitioner may receive repayment from the entity described in subsection (g)(4) for reasonable expenses incurred by the health care practitioner in the provision of the service to the individual, which may include travel expenses to or from the site of services.

(D) Before the service is provided, the health care practitioner or the entity described in subsection (g)(4) posts a clear and conspicuous notice at the site where the service is provided of the extent to which the legal liability of the health care practitioner is limited pursuant to this subsection.

(E) At the time the service is provided, the health care practitioner is licensed or certified in accordance with applicable Federal and State laws regarding the provision of the service.

(F) At the time the service is provided, the entity described in subsection (g)(4) maintains relevant documentation certifying that the health care practitioner meets the requirements of this subsection.

(3) Subsection (g) (other than paragraphs (3) and (5) and subsections (h), (i), and (l) apply to a health care practitioner for purposes of this subsection to the same extent and in the same manner as such subsections apply to an officer, governing board member, employee, or contractor of an entity described in subsection (g)(4), subject to paragraph (4), and subject to the following:

(A) The first sentence of paragraph (1) applies in lieu of the first sentence of subsection (g)(1)(A).

(B) With respect to an entity described in subsection (g)(4), a health care practitioner is not a health professional volunteer at such entity unless the entity sponsors the health care practitioner. For purposes of this subsection, the entity shall be considered to be sponsoring the health care practitioner if—

(i) with respect to the health care practitioner, the entity submits to the Secretary

⁴So in original. Probably should be “subclause”.

an application meeting the requirements of subsection (g)(1)(D); and

(ii) the Secretary, pursuant to subsection (g)(1)(E), determines that the health care practitioner is deemed to be an employee of the Public Health Service.

(C) In the case of a health care practitioner who is determined by the Secretary pursuant to subsection (g)(1)(E) to be a health professional volunteer at such entity, this subsection applies to the health care practitioner (with respect to services performed on behalf of the entity sponsoring the health care practitioner pursuant to subparagraph (B)) for any cause of action arising from an act or omission of the health care practitioner occurring on or after the date on which the Secretary makes such determination.

(D) Subsection (g)(1)(F) applies to a health care practitioner for purposes of this subsection only to the extent that, in providing health services to an individual, each of the conditions specified in paragraph (2) is met.

(4)(A) Amounts in the fund established under subsection (k)(2) shall be available for transfer under subparagraph (C) for purposes of carrying out this subsection.

(B)(i) Not later than May 1 of each fiscal year, the Attorney General, in consultation with the Secretary, shall submit to the Congress a report providing an estimate of the amount of claims (together with related fees and expenses of witnesses) that, by reason of the acts or omissions of health professional volunteers, will be paid pursuant to this section during the calendar year that begins in the following fiscal year.

(ii) Subsection (k)(1)(B) applies to the estimate under clause (i) regarding health professional volunteers to the same extent and in the same manner as such subsection applies to the estimate under such subsection regarding officers, governing board members, employees, and contractors of entities described in subsection (g)(4).

(iii) The report shall include a summary of the data relied upon for the estimate in clause (i), including the number of claims filed and paid from the previous calendar year.

(C) Not later than December 31 of each fiscal year, the Secretary shall transfer from the fund under subsection (k)(2) to the appropriate accounts in the Treasury an amount equal to the estimate made under subparagraph (B) for the calendar year beginning in such fiscal year, subject to the extent of amounts in the fund.

(5)(A) This subsection shall take effect on October 1, 2017, except as provided in subparagraph (B) and paragraph (6).

(B) Effective on December 13, 2016—

(i) the Secretary may issue regulations for carrying out this subsection, and the Secretary may accept and consider applications submitted pursuant to paragraph (3)(B); and

(ii) reports under paragraph (4)(B) may be submitted to Congress.

(6) Beginning on October 1, 2022, this subsection shall cease to have any force or effect.

(July 1, 1944, ch. 373, title II, § 224, formerly § 223, as added Pub. L. 91-623, § 4, Dec. 31, 1970, 84 Stat.

1870; renumbered § 224, Pub. L. 92-157, title III, § 301(c), Nov. 18, 1971, 85 Stat. 463; amended Pub. L. 102-501, §§ 2-4, Oct. 24, 1992, 106 Stat. 3268-3270; Pub. L. 103-183, title VII, § 706(a), Dec. 14, 1993, 107 Stat. 2241; Pub. L. 104-73, §§ 2-5(b), 6-11, Dec. 26, 1995, 109 Stat. 777-781; Pub. L. 104-191, title I, § 194, Aug. 21, 1996, 110 Stat. 1988; Pub. L. 104-299, § 4(a)(1), Oct. 11, 1996, 110 Stat. 3644; Pub. L. 107-251, title VI, § 601(a), Oct. 26, 2002, 116 Stat. 1664; Pub. L. 107-296, title III, § 304(c), Nov. 25, 2002, 116 Stat. 2165; Pub. L. 108-20, § 3(a)-(i), Apr. 30, 2003, 117 Stat. 646-648; Pub. L. 108-163, § 2(m)(1), Dec. 6, 2003, 117 Stat. 2023; Pub. L. 111-148, title X, § 10608(a), Mar. 23, 2010, 124 Stat. 1014; Pub. L. 114-255, div. B, title IX, § 9025, Dec. 13, 2016, 130 Stat. 1254.)

REFERENCES IN TEXT

The references to section 254b of this title the first place appearing in subsecs. (g)(1)(G)(ii), (k)(2), and (n)(1)(C), were in the original references to section 329, meaning section 329 of act July 1, 1944, which was omitted in the general amendment of subpart I (§ 254b et seq.) of part D of subchapter II of this chapter by Pub. L. 104-299, § 2, Oct. 11, 1996, 110 Stat. 3626.

Section 256a of this title, referred to in subsecs. (g)(1)(G)(ii), (k)(2), and (n)(1)(C), was repealed by Pub. L. 104-299, § 4(a)(3), Oct. 11, 1996, 110 Stat. 3645.

The Social Security Act, referred to in subsecs. (m)(2) and (o)(4), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII and XIX of the Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

AMENDMENTS

2016—Subsec. (q). Pub. L. 114-255 added subsec. (q).

2010—Subsec. (o)(1). Pub. L. 111-148 inserted “, or an officer, governing board member, employee, or contractor of a free clinic shall in providing services for the free clinic,” after “to an individual”.

2003—Subsec. (g)(1)(G)(ii). Pub. L. 108-163 substituted “254b” for “254c, 254b(h)” before “, or”.

Subsec. (k)(2). Pub. L. 108-163 substituted “254b” for “254c, 254b(h)” before “and”.

Subsec. (n)(1)(C). Pub. L. 108-163 substituted “254b” for “254c, 254b(h)” before “, or”.

Subsec. (p)(2)(A)(ii). Pub. L. 108-20, § 3(i), substituted “paragraph (7)(A)” for “paragraph(8)(A)”.

Subsec. (p)(2)(C)(ii)(II). Pub. L. 108-20, § 3(a), substituted “has resided with, or has had contact with,” for “resides or has resided with”.

Subsec. (p)(2)(D). Pub. L. 108-20, § 3(b), added subpar. (D).

Subsec. (p)(3). Pub. L. 108-20, § 3(c), amended heading and text of par. (3) generally. Prior to amendment, text read as follows: “The remedy provided by subsection (a) of this section shall be exclusive of any other civil action or proceeding for any claim or suit this subsection encompasses.”

Subsec. (p)(5). Pub. L. 108-20, § 3(d), substituted “Covered person” for “Defendant” in heading.

Subsec. (p)(7)(A)(i)(II). Pub. L. 108-20, § 3(e), amended subcl. (II) generally. Prior to amendment, subcl. (II) read as follows: “vaccinia immune globulin used to control or treat the adverse effects of vaccinia inoculation; and”.

Subsec. (p)(7)(B). Pub. L. 108-20, § 3(f)(1), substituted “means a person” for “includes any person” in introductory provisions.

Subsec. (p)(7)(B)(ii). Pub. L. 108-20, § 3(f)(2), substituted “auspices—” for “auspices”, designated “such countermeasure was administered;” as subcl. (I), and added subcls. (II) to (IV).

Subsec. (p)(7)(B)(iv) to (viii). Pub. L. 108-20, § 3(f)(3), (4), added cls. (iv) to (viii) and struck out former cl. (iv)

which read as follows: “an official, agent, or employee of a person described in clause (i), (ii), or (iii).”

Subsec. (p)(7)(C). Pub. L. 108-20, §3(g), substituted “individual who—” for “individual who”, designated “is authorized to administer such countermeasure under the law of the State in which the countermeasure was administered.” as cl. (i), substituted “; or” for period at end of cl. (i), and added cl. (ii).

Subsec. (p)(7)(D). Pub. L. 108-20, §3(h), added subpar. (D).

2002—Subsecs. (g)(1)(G)(ii), (k)(2), (n)(1)(C). Pub. L. 107-251 substituted “254b(h)” for “256”.

Subsec. (p). Pub. L. 107-296 added subsec. (p).

1996—Subsec. (g)(4). Pub. L. 104-299 substituted “under section 254b of this title.” for “under any of the following grant programs:” and struck out subpars. (A) to (D) which read as follows:

“(A) Section 254b of this title (relating to grants for migrant health centers).

“(B) Section 254c of this title (relating to grants for community health centers).

“(C) Section 256 of this title (relating to grants for health services for the homeless).

“(D) Section 256a of this title (relating to grants for health services for residents of public housing).”

Subsec. (o). Pub. L. 104-191 added subsec. (o).

1995—Subsec. (g)(1). Pub. L. 104-73, §§3(1), 4, 5(a), designated existing provisions as subpar. (A), inserted “and subject to the approval by the Secretary of an application under subparagraph (D)” after “For purposes of this section”, substituted “an entity described in paragraph (4), and any officer, governing board member, or employee of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, governing board member, employee, or contractor” for “, an entity described in paragraph (4) and any officer, employee, or contractor (subject to paragraph (5)) of such an entity who is a physician or other licensed or certified health care practitioner shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer of the full amount estimated under subsection (k)(1)(A) of this section was made under subsection (k)(3) of this section (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, employee, or contractor”, and added subpars. (B) to (H).

Subsec. (g)(3). Pub. L. 104-73, §2(a), struck out at end “This subsection shall not apply with respect to a cause of action arising from an act or omission which occurs on or after January 1, 1996.”

Subsec. (g)(5)(B). Pub. L. 104-73, §8, amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: “in the case of an individual who normally performs on average less than 32½ hours of services per week for the entity for the period of the contract and is a licensed or certified provider of obstetrical services—

“(i) the individual’s medical malpractice liability insurance coverage does not extend to services performed by the individual for the entity under the contract, or

“(ii) the Secretary finds that patients to whom the entity furnishes services will be deprived of obstetrical services if such individual is not considered a contractor of the entity for purposes of paragraph (1).”

Subsec. (h). Pub. L. 104-73, §5(b)(1), in introductory provisions substituted “The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—” for “Notwithstanding subsection (g)(1) of this section, the Secretary, in consultation with the Attorney General, may not deem an entity described in subsection (g)(4) of this

section to be an employee of the Public Health Service Act for purposes of this section unless the entity—”.

Subsec. (h)(4). Pub. L. 104-73, §5(b)(2), substituted “will fully cooperate” for “has fully cooperated”.

Subsec. (i)(1). Pub. L. 104-73, §9, substituted “may on the record determine, after notice and opportunity for a full and fair hearing” for “may determine, after notice and opportunity for a hearing”.

Subsec. (k)(1)(A). Pub. L. 104-73, §2(b)(1), substituted “For each fiscal year” for “For each of the fiscal years 1993, 1994, and 1995” and struck out “(except that an estimate shall be made for fiscal year 1993 by December 31, 1992, subject to an adjustment within 90 days thereafter)” after “beginning of the year”.

Subsec. (k)(2). Pub. L. 104-73, §§2(b)(2), 10, substituted “for each fiscal year” for “for each of the fiscal years 1993, 1994, and 1995” and “\$10,000,000” for “\$30,000,000”.

Subsec. (k)(3). Pub. L. 104-73, §3(2), which directed amendment of subsec. (k)(3) by inserting “governing board member,” after “officer,” was executed by inserting such language after “officers,” to reflect the probable intent of Congress.

Subsec. (l). Pub. L. 104-73, §6, added subsec. (l).

Subsec. (m). Pub. L. 104-73, §7, added subsec. (m).

Subsec. (n). Pub. L. 104-73, §11, added subsec. (n).

1993—Subsec. (k)(2). Pub. L. 103-183 inserted at end “Appropriations for purposes of this paragraph shall be made separate from appropriations made for purposes of sections 254b, 254c, 256 and 256a of this title.”

1992—Subsecs. (g) to (k). Pub. L. 102-501 added subsecs. (g) to (k).

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111-148, title X, §10608(b), Mar. 23, 2010, 124 Stat. 1014, provided that: “The amendment made by this section [amending this section] shall take effect on the date of enactment of this Act [Mar. 23, 2010] and apply to any act or omission which occurs on or after that date.”

EFFECTIVE DATE OF 2003 AMENDMENTS

Pub. L. 108-163, §3, Dec. 6, 2003, 117 Stat. 2023, provided that: “This Act [see Short Title of 2003 Amendments note set out under section 201 of this title] is deemed to have taken effect immediately after the enactment of Public Law 107-251 [Oct. 26, 2002].”

Pub. L. 108-20, §3(j), Apr. 30, 2003, 117 Stat. 649, provided that: “This section [amending this section] shall take effect as of November 25, 2002.”

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107-296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107-296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104-299, §5, Oct. 11, 1996, 110 Stat. 3645, as amended by Pub. L. 104-208, div. A, title I, §101(e) [title V, §521], Sept. 30, 1996, 110 Stat. 3009-233, 3009-275, provided that: “This Act [enacting sections 254b and 254c of this title, amending this section and sections 256c, 1395x, and 1396d of this title, repealing sections 256 and 256a of this title, and enacting provisions set out as notes under sections 201 and 254b of this title] and the amendments made by this Act shall become effective on October 1, 1996.”

[Pub. L. 104-208, div. A, title I, §101(e) [title V, §521], Sept. 30, 1996, 110 Stat. 3009-233, 3009-275, provided that the amendment made by that section is effective on the day after Oct. 11, 1996.]

EFFECTIVE DATE OF 1995 AMENDMENT

Pub. L. 104-73, §5(c), Dec. 26, 1995, 109 Stat. 779, provided that: “If, on the day before the date of the enactment of this Act [Dec. 26, 1995], an entity was deemed to be an employee of the Public Health Service for purposes of section 224(g) of the Public Health Service Act [42 U.S.C. 233(g)], the condition under paragraph (1)(D)

of such section (as added by subsection (a) of this section) that an application be approved with respect to the entity does not apply until the expiration of the 180-day period beginning on such date.”

EFFECTIVE DATE OF 1992 AMENDMENT

Pub. L. 102-501, § 6, Oct. 24, 1992, 106 Stat. 3272, provided that: “The amendments made by this Act [amending this section] shall take effect on the date of the enactment of this Act [Oct. 24, 1992].”

REPORT ON RISK EXPOSURE OF COVERED ENTITIES

Pub. L. 102-501, § 5, Oct. 24, 1992, 106 Stat. 3271, provided that:

“(a) IN GENERAL.—Not later than April 1, 1995, the Attorney General, in consultation with the Secretary of Health and Human Services (hereafter referred to as the ‘Secretary’), shall submit a report to Congress on the medical malpractice liability claims experience of entities subject to section 224(g) of the Public Health Service Act [42 U.S.C. 233(g)] (as added by section 2(a)) and the risk exposure associated with such entities.

“(b) EFFECT OF LIABILITY PROTECTIONS ON COSTS INCURRED BY COVERED ENTITIES.—The Attorney General’s report under subsection (a) shall include an analysis by the Secretary comparing—

“(1) the Secretary’s estimate of the aggregate amounts that such entities (together with the officers, employees, and contractors of such entities who are subject to section 224(g) of such Act) would have directly or indirectly paid to obtain medical malpractice liability insurance coverage had section 224(g) of the Public Health Service Act not been enacted into law, with

“(2) the aggregate amounts by which the grants received by such entities under the Public Health Service Act [42 U.S.C. 201 et seq.] were reduced as a result of the enactment of section 224(k)(2) of such Act [42 U.S.C. 233(k)(2)].”

§ 234. Repealed. Pub. L. 94-484, title IV, § 408(b)(1), Oct. 12, 1976, 90 Stat. 2281, eff. Oct. 1, 1977

Section, act July 1, 1944, ch. 373, title II, § 225, as added Oct. 27, 1972, Pub. L. 92-585, § 5, 86 Stat. 1293; amended Aug. 23, 1974, Pub. L. 93-385, § 1, 88 Stat. 741; Apr. 22, 1976, Pub. L. 94-278, title IX, § 901, 90 Stat. 415; Sept. 30, 1976, Pub. L. 94-437, title I, § 104, 90 Stat. 1403; Oct. 12, 1976, Pub. L. 94-484, title I, § 101(t), 90 Stat. 2246, related to Public Health and National Health Service Corps Scholarship Training program.

§ 235. Administration of grants in multigrant projects; promulgation of regulations

For the purpose of facilitating the administration of, and expediting the carrying out of the purposes of, the programs established by subchapters V, VI, and VII,¹ and sections 242b, 246(a), 246(b), 246(c), 246(d),¹ and 246(e)¹ of this title in situations in which grants are sought or made under two or more of such programs with respect to a single project, the Secretary is authorized to promulgate regulations—

(1) under which the administrative functions under such programs with respect to such project will be performed by a single administrative unit which is the administrative unit charged with the administration of any of such programs or is the administrative unit charged with the supervision of two or more of such programs;

(2) designed to reduce the number of applications, reports, and other materials required

under such programs to be submitted with respect to such project, and otherwise to simplify, consolidate, and make uniform (to the extent feasible), the data and information required to be contained in such applications, reports, and other materials; and

(3) under which inconsistent or duplicative requirements imposed by such programs will be revised and made uniform with respect to such project;

except that nothing in this section shall be construed to authorize the Secretary to waive or suspend, with respect to any such project, any requirement with respect to any of such programs if such requirement is imposed by law or by any regulation required by law.

(July 1, 1944, ch. 373, title II, § 226, formerly title III, § 310A, as added Pub. L. 91-515, title II, § 270, Oct. 30, 1970, 84 Stat. 1306; amended Pub. L. 92-157, title II, § 201, Nov. 18, 1971, 85 Stat. 461; renumbered § 226, Pub. L. 93-353, title I, § 102(e), July 23, 1974, 88 Stat. 362.)

REFERENCES IN TEXT

Subchapters V and VI, referred to in text, are classified to sections 292 et seq. and 296 et seq., respectively, of this title.

Subchapter VII, referred to in text, which was classified to section 299 et seq. of this title, was repealed by Pub. L. 99-117, § 12(d), Oct. 7, 1985, 99 Stat. 495.

Section 246(d) of this title, referred to in text, was repealed by Pub. L. 97-35, title IX, § 902(b), Aug. 13, 1981, 95 Stat. 559.

Section 246(e) of this title, referred to in text, was repealed by Pub. L. 94-63, title V, § 501(b), July 29, 1975, 89 Stat. 346.

CODIFICATION

Section was formerly classified to section 242i of this title.

AMENDMENTS

1971—Pub. L. 92-157 provided for administration of programs established under subchapters V and VI of this chapter.

§ 236. Orphan Products Board

(a) Establishment; composition; chairman

There is established in the Department of Health and Human Services a board for the development of drugs (including biologics) and devices (including diagnostic products) for rare diseases or conditions to be known as the Orphan Products Board. The Board shall be comprised of the Assistant Secretary for Health of the Department of Health and Human Services and representatives, selected by the Secretary, of the Food and Drug Administration, the National Institutes of Health, the Centers for Disease Control and Prevention, and any other Federal department or agency which the Secretary determines has activities relating to drugs and devices for rare diseases or conditions. The Assistant Secretary for Health shall chair the Board.

(b) Function

The function of the Board shall be to promote the development of drugs and devices for rare diseases or conditions and the coordination among Federal, other public, and private agencies in carrying out their respective functions

¹ See References in Text note below.