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] of this chapter, 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; re-

[1] See References in Text note below.

numbered § 226, Pub. L. 93–353, title I, § 102(e), July 23, 1974, 88 Stat. 362.)

REFERENCES IN TEXT

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

Subchapter VII of this chapter, 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 relating to the development of such articles for such diseases or conditions.

(c) Duties with respect to drugs for rare diseases or conditions

In the case of drugs for rare diseases or conditions the Board shall—

(1) evaluate—

(A) the effect of subchapter B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360aa et seq.] on the development of such drugs, and

(B) the implementation of such subchapter; [1]

(2) evaluate the activities of the National Institutes of Health for the development of drugs for such diseases or conditions,

(3) assure appropriate coordination among the Food and Drug Administration, the National Institutes of Health and the Centers for Disease Control and Prevention in the carrying out of their respective functions relating to the development of drugs for such diseases or conditions to assure that the activities of each agency are complementary,

(4) assure appropriate coordination among all interested Federal agencies, manufacturers, and organizations representing patients, in their activities relating to such drugs,

(5) with the consent of the sponsor of a drug for a rare disease or condition exempt under section 505(i) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i)] or regulations issued under such section, inform physicians and the public respecting the availability of such drug for such disease or condition and inform physicians and the public respecting the availability of drugs approved under section 505(c) of such Act [21 U.S.C. 355(c)] or licensed under section 262 of this title for rare diseases or conditions,

(6) seek business entities and others to undertake the sponsorship of drugs for rare diseases or conditions, seek investigators to facilitate the development of such drugs, and seek business entities to participate in the distribution of such drugs, and

(7) recognize the efforts of public and private entities and individuals in seeking the development of drugs for rare diseases or conditions and in developing such drugs.

(d) Consultation

The Board shall consult with interested persons respecting the activities of the Board under this section and as part of such consultation shall provide the opportunity for the submission of oral views.

(e) Annual report; contents

The Board shall submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives an annual report—

(1) identifying the drugs which have been designated under section 526 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bb] for a rare disease or condition,

(2) describing the activities of the Board, and

(3) containing the results of the evaluations carried out by the Board.

The Director of the National Institutes of Health shall submit to the Board for inclusion in the annual report a report on the rare disease and condition research activities of the Institutes of the National Institutes of Health; the Secretary of the Treasury shall submit to the Board for inclusion in the annual report a report on the use of the credit against tax provided by section 44H [2] of title 26; and the Secretary of Health and Human Services shall submit to the Board for inclusion in the annual report a report on the program of assistance under section 360ee of title 21 for the development of drugs for rare diseases and conditions. Each annual report

[1] So in original. The semicolon probably should be a comma.

[2] See References in Text note below.