(e) Effective date

(1) In general

This section shall take effect 90 days after June 24, 2019.

(2) Application

This section shall apply to a claim for harm only if the act or omission that caused such harm occurred on or after the effective date described in paragraph (1).

(July 1, 1944, ch. 373, title II, § 225, as added Pub. L. 116–22, title II, § 208(a), June 24, 2019, 133 Stat. 927.)

Editorial Notes

REFERENCES IN TEXT

The Volunteer Protection Act of 1997, referred to in subsec. (b), is Pub. L. 105–19, June 18, 1997, 111 Stat. 218, which is classified generally to chapter 139 (§ 14501 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 14501 of this title and Tables.

PRIOR PROVISIONS

A former section 234, 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, prior to repeal by Pub. L. 94–484, title IV, § 408(b)(1), Oct. 12, 1976, 90 Stat. 2281, effective Oct. 1, 1977.

Statutory Notes and Related Subsidiaries

LIMITATION ON LIABILITY FOR VOLUNTEER HEALTH CARE PROFESSIONALS DURING COVID–19 EMERGENCY RESPONSE

Pub. L. 116–136, div. A, title III, § 3215, Mar. 27, 2020, 134 Stat. 374, provided that:

''(a) LIMITATION ON LIABILITY.—Except as provided in subsection (b), a health care professional shall not be liable under Federal or State law for any harm caused by an act or omission of the professional in the provision of health care services during the public health emergency with respect to COVID–19 declared by the Secretary of Health and Human Services (referred to in this section as the 'Secretary') under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020, if—

''(1) the professional is providing health care services in response to such public health emergency, as a volunteer; and

''(2) the act or omission occurs—

''(A) in the course of providing health care services;

''(B) in the health care professional's capacity as a volunteer;

''(C) in the course of providing health care services that—

''(i) are within the scope of the license, registration, or certification of the volunteer, as defined by the State of licensure, registration, or certification; and

''(ii) do not exceed the scope of license, registration, or certification of a substantially similar health professional in the State in which such act or omission occurs; and

''(D) in a good faith belief that the individual being treated is in need of health care services.

''(b) EXCEPTIONS.—Subsection (a) does not apply if—

''(1) the harm was caused by an act or omission constituting willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious flagrant indifference to the rights or safety of the individual harmed by the health care professional; or

''(2) the health care professional rendered the health care services under the influence (as determined pursuant to applicable State law) of alcohol or an intoxicating drug.

''(c) PREEMPTION.—

''(1) IN GENERAL.—This section preempts the laws of a State or any political subdivision of a State to the extent that such laws are inconsistent with this section, unless such laws provide greater protection from liability.

''(2) VOLUNTEER PROTECTION ACT.—Protections afforded by this section are in addition to those provided by the Volunteer Protection Act of 1997 (Public Law 105–19) [42 U.S.C. 14501 et seq.].

''(d) DEFINITIONS.—In this section—

''(1) the term 'harm' includes physical, nonphysical, economic, and noneconomic losses;

''(2) the term 'health care professional' means an individual who is licensed, registered, or certified under Federal or State law to provide health care services;

''(3) the term 'health care services' means any services provided by a health care professional, or by any individual working under the supervision of a health care professional that relate to—

''(A) the diagnosis, prevention, or treatment of COVID–19; or

''(B) the assessment or care of the health of a human being related to an actual or suspected case of COVID–19; and

''(4) the term 'volunteer' means a health care professional who, with respect to the health care services rendered, does not receive compensation or any other thing of value in lieu of compensation, which compensation—

''(A) includes a payment under any insurance policy or health plan, or under any Federal or State health benefits program; and

''(B) excludes—

''(i) receipt of items to be used exclusively for rendering health care services in the health care professional's capacity as a volunteer described in subsection (a)(1); and

''(ii) any reimbursement for travel to the site where the volunteer services are rendered and any payments in cash or kind to cover room and board, if services are being rendered more than 75 miles from the volunteer's principal place of residence.

''(e) EFFECTIVE DATE.—This section shall take effect upon the date of enactment of this Act [Mar. 27, 2020], and applies to a claim for harm only if the act or omission that caused such harm occurred on or after the date of enactment.

''(f) SUNSET.—This section shall be in effect only for the length of the public health emergency declared by the Secretary of Health and Human Services (referred to in this section as the 'Secretary') under section 319 of the Public Health Service Act (42 U.S.C. 247d) on January 31, 2020 with respect to COVID–19.''

§ 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

[1] See References in Text note below.

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.)

Editorial Notes

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 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.

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