

than \$20,000 of the principal and interest of the educational loans of such health professionals.

(2) Limitation

The Secretary may not enter into an agreement with a health professional pursuant to paragraph (1) unless such professional—

- (A) has a substantial amount of educational loans relative to income; and
- (B) agrees to serve as an employee of the Food and Drug Administration for purposes of paragraph (1) for a period of not less than 3 years.

(b) Applicability of certain provisions

With respect to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III of the Public Health Service Act [42 U.S.C. 254l et seq.], the provisions of such subpart shall, except as inconsistent with subsection (a) of this section, apply to the program established in such subsection in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program.

(c) Authorization of appropriations

For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1994 through 1996.

(June 25, 1938, ch. 675, §1005, formerly §905, as added Pub. L. 103-43, title XX, §2006(2), June 10, 1993, 107 Stat. 210; renumbered §1005, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b), is act July 1, 1944, ch. 373, 58 Stat. 682. Subpart III of part D of title III of the Act is classified generally to subpart III [§254l et seq.] of part D of subchapter II of chapter 6A of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§ 396. Practice of medicine

Nothing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.

(June 25, 1938, ch. 675, §1006, formerly §906, as added Pub. L. 105-115, title II, §214, Nov. 21, 1997, 111 Stat. 2348; renumbered §1006, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 397. Contracts for expert review

(a) In general

(1) Authority

The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this chapter for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 379 of this title relating to the confidentiality of information.

(2) Increased efficiency and expertise through contracts

The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

(b) Review of expert review

(1) In general

Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

(2) Limitation

A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this chapter or in the Public Health Service Act (42 U.S.C. 201 et seq.).

(June 25, 1938, ch. 675, §1007, formerly §907, as added Pub. L. 105-115, title IV, §415, Nov. 21, 1997, 111 Stat. 2377; renumbered §1007, Pub. L. 111-31,

div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

Editorial Notes

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(2), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105-115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§ 398. Notices to States regarding imported food

(a) In general

If the Secretary has credible evidence or information indicating that a shipment of imported food or portion thereof presents a threat of serious adverse health consequences or death to humans or animals, the Secretary shall provide notice regarding such threat to the States in which the food is held or will be held, and to the States in which the manufacturer, packer, or distributor of the food is located, to the extent that the Secretary has knowledge of which States are so involved. In providing notice to a State, the Secretary shall request the State to take such action as the State considers appropriate, if any, to protect the public health regarding the food involved.

(b) Rule of construction

Subsection (a) may not be construed as limiting the authority of the Secretary with respect to food under any other provision of this chapter.

(June 25, 1938, ch. 675, §1008, formerly §908, as added Pub. L. 107-188, title III, §310, June 12, 2002, 116 Stat. 673; renumbered §1008, Pub. L. 111-31, div. A, title I, §101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 399. Grants to enhance food safety

(a) In general

The Secretary is authorized to make grants to eligible entities to—

- (1) undertake examinations, inspections, and investigations, and related food safety activities under section 372 of this title;
- (2) train to the standards of the Secretary for the examination, inspection, and investigation of food manufacturing, processing, packing, holding, distribution, and importation, including as such examination, inspection, and investigation relate to retail food establishments;
- (3) build the food safety capacity of the laboratories of such eligible entity, including the detection of zoonotic diseases;
- (4) build the infrastructure and capacity of the food safety programs of such eligible entity to meet the standards as outlined in the grant application; and

(5) take appropriate action to protect the public health in response to—

(A) a notification under section 398 of this title, including planning and otherwise preparing to take such action; or

(B) a recall of food under this chapter.

(b) Eligible entities; application

(1) In general

In this section, the term “eligible entity” means an entity—

(A) that is—

- (i) a State;
- (ii) a locality;
- (iii) a territory;
- (iv) an Indian tribe (as defined in section 5304(e) of title 25); or
- (v) a nonprofit food safety training entity that collaborates with 1 or more institutions of higher education; and

(B) that submits an application to the Secretary at such time, in such manner, and including such information as the Secretary may reasonably require.

(2) Contents

Each application submitted under paragraph (1) shall include—

- (A) an assurance that the eligible entity has developed plans to engage in the types of activities described in subsection (a);
- (B) a description of the types of activities to be funded by the grant;
- (C) an itemization of how grant funds received under this section will be expended;
- (D) a description of how grant activities will be monitored; and
- (E) an agreement by the eligible entity to report information required by the Secretary to conduct evaluations under this section.

(c) Limitations

The funds provided under subsection (a) shall be available to an eligible entity that receives a grant under this section only to the extent such entity funds the food safety programs of such entity independently of any grant under this section in each year of the grant at a level equal to the level of such funding in the previous year, increased by the Consumer Price Index. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

(d) Additional authority

The Secretary may—

(1) award a grant under this section in each subsequent fiscal year without reapplication for a period of not more than 3 years, provided the requirements of subsection (c) are met for the previous fiscal year; and

(2) award a grant under this section in a fiscal year for which the requirement of subsection (c) has not been met only if such requirement was not met because such funding was diverted for response to 1 or more natural disasters or in other extenuating circumstances that the Secretary may determine appropriate.