

(Pub. L. 107-109, § 6, Jan. 4, 2002, 115 Stat. 1414; Pub. L. 110-85, title III, § 306(a), Sept. 27, 2007, 121 Stat. 864; Pub. L. 112-144, title V, § 511, July 9, 2012, 126 Stat. 1050.)

CODIFICATION

Section was enacted as part of the Best Pharmaceuticals for Children Act, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

AMENDMENTS

2012—Subsec. (c)(2) to (4). Pub. L. 112-144, § 511(1), added pars. (2) and (3) and redesignated former par. (2) as (4).

Subsec. (d). Pub. L. 112-144, § 511(2), added subsec. (d).
2007—Subsec. (b). Pub. L. 110-85 inserted “, including increasing pediatric access to medical devices” before period at end.

§ 394. Scientific review groups

Without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this chapter); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(June 25, 1938, ch. 675, § 1004, formerly § 903, as added Pub. L. 101-635, title III, § 301, Nov. 28, 1990, 104 Stat. 4584; renumbered § 904, Pub. L. 103-43, title XX, § 2006(1), June 10, 1993, 107 Stat. 209; renumbered § 1004, Pub. L. 111-31, div. A, title I, § 101(b)(2), June 22, 2009, 123 Stat. 1784.)

§ 395. Loan repayment program

(a) In general

(1) Authority for program

Subject to paragraph (2), the Secretary shall carry out a program of entering into contracts with appropriately qualified health professionals under which such health professionals agree to conduct research, as employees of the Food and Drug Administration, in consideration of the Federal Government agreeing to repay, for each year of such service, not more 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. 254f 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.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended. Subpart III of part D of title III of the Act is classified generally to subpart III [§ 254f 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.)

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 ap-