(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. 254*l* 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 [§254*l* 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 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