

ernment while also considering initiatives at the State and local levels and in the private sector.

(d) Annual report

The Secretary shall, on an annual basis, submit to Congress a report concerning the activities and findings with respect to research supported under this section.

(Pub. L. 111-148, title IV, § 4301, Mar. 23, 2010, 124 Stat. 578.)

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Public Health Service Act which comprises this chapter.

SUBCHAPTER XVI—PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIOR RESEARCH

§ 300v. Commission

(a) Establishment; composition; appointment of members; vacancies

(1) There is established the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (hereinafter in this subchapter referred to as the "Commission") which shall be composed of eleven members appointed by the President. The members of the Commission shall be appointed as follows:

(A) Three of the members shall be appointed from individuals who are distinguished in biomedical or behavioral research.

(B) Three of the members shall be appointed from individuals who are distinguished in the practice of medicine or otherwise distinguished in the provision of health care.

(C) Five of the members shall be appointed from individuals who are distinguished in one or more of the fields of ethics, theology, law, the natural sciences (other than a biomedical or behavioral science), the social sciences, the humanities, health administration, government, and public affairs.

(2) No individual who is a full-time officer or employee of the United States may be appointed as a member of the Commission. The Secretary of Health and Human Services, the Secretary of Defense, the Director of Central Intelligence, the Director of the Office of Science and Technology Policy, the Secretary of Veterans Affairs, and the Director of the National Science Foundation shall each designate an individual to provide liaison with the Commission.

(3) No individual may be appointed to serve as a member of the Commission if the individual has served for two terms of four years each as such a member.

(4) A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(b) Terms of members

(1) Except as provided in paragraphs (2) and (3), members shall be appointed for terms of four years.

(2) Of the members first appointed—

(A) four shall be appointed for terms of three years, and

(B) three shall be appointed for terms of two years,

as designated by the President at the time of appointment.

(3) Any member appointed to fill a vacancy occurring before the expiration of the term for which his predecessor was appointed shall be appointed only for the remainder of such term. A member may serve after the expiration of his term until his successor has taken office.

(c) Chairman

The Chairman of the Commission shall be appointed by the President, by and with the advice and consent of the Senate, from members of the Commission.

(d) Meetings

(1) Seven members of the Commission shall constitute a quorum for business, but a lesser number may conduct hearings.

(2) The Commission shall meet at the call of the Chairman or at the call of a majority of its members.

(e) Compensation; travel expenses, etc.

(1) Members of the Commission shall each be entitled to receive the daily equivalent of the annual rate of basic pay in effect for grade GS-18 of the General Schedule for each day (including travel time) during which they are engaged in the actual performance of duties vested in the Commission.

(2) While away from their homes or regular places of business in the performance of services for the Commission, members of the Commission shall be allowed travel expenses, including per diem in lieu of subsistence, in the same manner as persons employed intermittently in the Government service are allowed expenses under section 5703 of title 5.

(July 1, 1944, ch. 373, title XVIII, § 1801, as added Pub. L. 95-622, title III, § 301, Nov. 9, 1978, 92 Stat. 3437; amended Pub. L. 96-88, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 100-527, § 10(1), Oct. 25, 1988, 102 Stat. 2640.)

AMENDMENTS

1988—Subsec. (a)(2). Pub. L. 100-527 substituted "Secretary of Veterans Affairs" for "Administrator of Veterans' Affairs".

CHANGE OF NAME

Reference to the Director of Central Intelligence or the Director of the Central Intelligence Agency in the Director's capacity as the head of the intelligence community deemed to be a reference to the Director of National Intelligence. Reference to the Director of Central Intelligence or the Director of the Central Intelligence Agency in the Director's capacity as the head of the Central Intelligence Agency deemed to be a reference to the Director of the Central Intelligence Agency. See section 1081(a), (b) of Pub. L. 108-458, set out as a note under section 3001 of Title 50, War and National Defense.

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsec. (a)(2) pursuant to section 509(b) of Pub. L. 96-88, which is classified to section 3508(b) of Title 20, Education.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-527 effective Mar. 15, 1989, see section 18(a) of Pub. L. 100-527, set out as a Depart-

ment of Veterans Affairs Act note under section 301 of Title 38, Veterans' Benefits.

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

APPOINTMENT OF INITIAL MEMBERS

Section 302(a) of Pub. L. 95-622 directed President to initially appoint members to President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (established under the amendment made by section 301) [enacting this subchapter] not later than 90 days after Nov. 9, 1978.

EXECUTIVE ORDER NO. 12184

Ex. Ord. No. 12184, Dec. 17, 1979, 44 F.R. 75091, which established the President's Special Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, was revoked by Ex. Ord. No. 12553, Feb. 25, 1986, 51 F.R. 7237.

§ 300v-1. Duties of Commission

(a) Studies and investigations; priority and order; report to President and Congress

(1) The Commission shall undertake studies of the ethical and legal implications of—

(A) the requirements for informed consent to participation in research projects and to otherwise undergo medical procedures;

(B) the matter of defining death, including the advisability of developing a uniform definition of death;

(C) voluntary testing, counseling, and information and education programs with respect to genetic diseases and conditions, taking into account the essential equality of all human beings, born and unborn;

(D) the differences in the availability of health services as determined by the income or residence of the persons receiving the services;

(E) current procedures and mechanisms designed (i) to safeguard the privacy of human subjects of behavioral and biomedical research, (ii) to ensure the confidentiality of individually identifiable patient records, and (iii) to ensure appropriate access of patients to information continued¹ in such records,² and

(F) such other matters relating to medicine or biomedical or behavioral research as the President may designate for study by the Commission.

The Commission shall determine the priority and order of the studies required under this paragraph.

(2) The Commission may undertake an investigation or study of any other appropriate matter which relates to medicine or biomedical or behavioral research (including the protection of human subjects of biomedical or behavioral research) and which is consistent with the purposes of this subchapter on its own initiative or at the request of the head of a Federal agency.

¹ So in original. Probably should be "contained".

² So in original. The comma probably should be a semicolon.

(3) In order to avoid duplication of effort, the Commission may, in lieu of, or as part of, any study or investigation required or otherwise conducted under this subsection, use a study or investigation conducted by another entity if the Commission sets forth its reasons for such use.

(4) Upon the completion of each investigation or study undertaken by the Commission under this subsection (including a study or investigation which merely uses another study or investigation), it shall report its findings (including any recommendations for legislation or administrative action) to the President and the Congress and to each Federal agency to which a recommendation in the report applies.

(b) Recommendations to agencies; subsequent administrative requirements

(1) Within 60 days of the date a Federal agency receives a recommendation from the Commission that the agency take any action with respect to its rules, policies, guidelines, or regulations, the agency shall publish such recommendation in the Federal Register and shall provide opportunity for interested persons to submit written data, views, and arguments with respect to adoption of the recommendation.

(2) Within the 180-day period beginning on the date of such publication, the agency shall determine whether the action proposed by such recommendation is appropriate, and, to the extent that it determines that—

(A) such action is not appropriate, the agency shall, within such time period, provide the Commission with, and publish in the Federal Register, a notice of such determination (including an adequate statement of the reasons for the determination), or

(B) such action is appropriate, the agency shall undertake such action as expeditiously as feasible and shall notify the Commission of the determination and the action undertaken.

(c) Report on protection of human subjects; scope; submission to President, etc.

The Commission shall biennially report to the President, the Congress, and appropriate Federal agencies on the protection of human subjects of biomedical and behavioral research. Each such report shall include a review of the adequacy and uniformity (1) of the rules, policies, guidelines, and regulations of all Federal agencies regarding the protection of human subjects of biomedical or behavioral research which such agencies conduct or support, and (2) of the implementation of such rules, policies, guidelines, and regulations by such agencies, and may include such recommendations for legislation and administrative action as the Commission deems appropriate.

(d) Annual report; scope; submission to President, etc.

Not later than December 15 of each year (beginning with 1979) the Commission shall report to the President, the Congress, and appropriate Federal agencies on the activities of the Commission during the fiscal year ending in such year. Each such report shall include a complete list of all recommendations described in subsection (b)(1) of this section made to Federal agencies by the Commission during the fiscal