

ATTACHMENT A

Legal Authority

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TITLE 42--THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A--PUBLIC HEALTH SERVICE
SUBCHAPTER II--GENERAL POWERS AND DUTIES
Part A--Research and Investigations

Sec. 241. Research and investigations generally

(a) Authority of Secretary

The Secretary shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Secretary is authorized to--

(1) collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

(2) make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

(3) make grants-in-aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the advisory council to the entity of the Department supporting such projects and make, upon recommendation of the advisory council to the appropriate entity of the Department, grants-in-aid to public or

nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research;

(4) secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

(5) for purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment;

(6) make available, to health officials, scientists, and appropriate public and other nonprofit institutions and organizations, technical advice and assistance on the application of statistical methods to experiments, studies, and surveys in health and medical fields;

(7) enter into contracts, including contracts for research in accordance with and subject to the provisions of law applicable to contracts entered into by the military departments under sections

2353 and 2354 of title 10, except that determination, approval, and certification required thereby shall be by the Secretary of Health and Human Services; and

(8) adopt, upon recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers necessary or appropriate to carry out the purposes of this section.

The Secretary may make available to individuals and entities, for biomedical and behavioral research, substances and living organisms.

Such substances and organisms shall be made available under such terms and conditions (including payment for them) as the Secretary determines appropriate.

(b) Testing for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects; consultation

(1) The Secretary shall conduct and may support through grants and contracts studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects. In carrying out this paragraph, the Secretary shall consult with entities of the Federal Government, outside of the Department of Health and Human

Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct for such entity studies and testing of substances for carcinogenicity, teratogenicity, mutagenicity, and other harmful biological effects.

(2)(A) The Secretary shall establish a comprehensive program of research into the biological effects of low-level ionizing radiation under which program the Secretary shall conduct such research and may support such research by others through grants and contracts.

(B) The Secretary shall conduct a comprehensive review of Federal programs of research on the biological effects of ionizing radiation.

(3) The Secretary shall conduct and may support through grants and contracts research and studies on human nutrition, with particular emphasis on the role of nutrition in the prevention and treatment of disease and on the maintenance and promotion of health, and programs for the dissemination of information respecting human nutrition to health professionals and the public. In carrying out activities under this paragraph, the Secretary shall provide for the coordination of such of these activities as are performed by the different divisions within the Department of Health and Human Services and shall consult with entities of the Federal Government, outside of the Department of Health and Human Services, engaged in comparable activities. The Secretary, upon request of such an entity and under appropriate arrangements for the payment of expenses, may conduct and support such activities for such entity.

(4) The Secretary shall publish a biennial report which contains--

(A) a list of all substances (i) which either are known to be carcinogens or may reasonably be anticipated to be carcinogens and (ii) to which a significant number of persons residing in the United States are exposed;

(B) information concerning the nature of such exposure and the estimated number of persons exposed to such substances;

(C) a statement identifying (i) each substance contained in the list under subparagraph (A) for which no effluent, ambient, or exposure standard has been established by a Federal agency, and (ii) for each effluent, ambient, or exposure standard established by a

Federal agency with respect to a substance contained in the list under subparagraph (A), the extent to which, on

the basis of available medical, scientific, or other data, such standard, and the implementation of such standard by the agency, decreases the risk to public health from exposure to the substance; and

(D) a description of (i) each request received during the year involved--

(I) from a Federal agency outside the Department of Health and Human Services for the Secretary, or

(II) from an entity within the Department of Health and Human Services to any other entity within the Department, to conduct research into, or testing for, the carcinogenicity of substances or to provide information described in clause (ii) of subparagraph (C), and (ii) how the Secretary and each such other entity, respectively, have responded to each such request.

(5) The authority of the Secretary to enter into any contract for the conduct of any study, testing, program, research, or review, or assessment under this subsection shall be effective for any fiscal year only to such extent or in such amounts as are provided in advance in appropriation Acts.

(c) Diseases not significantly occurring in United States

The Secretary may conduct biomedical research, directly or through grants or contracts, for the identification, control, treatment, and prevention of diseases (including tropical diseases) which do not occur to a significant extent in the United States.

(d) Protection of privacy of individuals who are research subjects

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.

(July 1, 1944, ch. 373, title III, Sec. 301, 58 Stat. 691; July 3, 1946, ch. 538, Sec. 7(a), (b), 60 Stat. 423; June 16, 1948, ch. 481, Sec. 4(e), (f), 62 Stat. 467; June 24, 1948, ch. 621, Sec. 4(e), (f), 62 Stat. 601; June 25, 1948, ch. 654, Sec. 1, 62 Stat. 1017; July 3, 1956, ch. 510, Sec. 4, 70 Stat. 490; Pub. L. 86-798, Sept. 15, 1960, 74 Stat. 1053; Pub. L. 87-838, Sec. 2, Oct. 17, 1962, 76 Stat. 1073; Pub. L. 89-115, Sec. 3, Aug. 9, 1965, 79 Stat. 448; Pub. L. 90-174, Sec. 9, Dec. 5, 1967, 81 Stat. 540; Pub. L. 91-513, title I, Sec. 3(a), Oct. 27, 1970, 84 Stat. 1241; Pub. L. 91-515, title II, Sec. 292, Oct. 30, 1970, 84 Stat. 1308; Pub. L. 92-218, Sec. 6(a)(2), Dec. 23, 1971, 85 Stat. 785; Pub. L. 92-423, Sec. 7(b), Sept. 19, 1972, 86 Stat. 687; Pub. L. 93-282, title I, Sec. 122(b), May 14, 1974, 88 Stat. 132; Pub. L. 93-348, title I, Sec. 104(a)(1), July 12, 1974, 88 Stat. 346; Pub. L. 93-352, title I, Sec. 111, July 23, 1974, 88 Stat. 360; Pub. L. 94-278, title I, Sec. 111, Apr. 22, 1976, 90 Stat. 405; Pub. L. 95-622, title II, Secs. 261, 262, Nov. 9, 1978, 92 Stat. 3434; Pub. L. 96-88, title V, Sec. 509(b), Oct. 17, 1979, 93 Stat. 695; Pub. L. 99-158, Sec. 3(a)(5), Nov. 20, 1985, 99 Stat. 879; Pub. L. 99-570, title IV, Sec. 4021(b)(2), Oct. 27, 1986, 100 Stat. 3207-124; Pub. L. 99-660, title I, Sec. 104, Nov. 14, 1986, 100 Stat. 3751; Pub. L. 100-607, title I, Sec. 163(1), (2), Nov. 4, 1988, 102 Stat. 3062; Pub. L. 103-43, title XX, Sec. 2009, June 10, 1993, 107 Stat. 213.)

Amendments

1993--Subsec. (b)(4). Pub. L. 103-43 substituted ``a biennial report'' for ``an annual report'' in introductory provisions.

1988--Subsec. (d). Pub. L. 100-607 redesignated concluding provisions of subsec. (a) of section 242a of this title as subsec. (d) of this section, substituted ``biomedical, behavioral, clinical, or other research (including research on mental health, including'' for ``research on mental health, including'', and substituted ``drugs)'' for ``drugs,''.

1986--Subsec. (a)(3). Pub. L. 99-570 struck out ``or, in the case of mental health projects, by the National Advisory Mental Health Council;'' after ``Department supporting such projects'' and struck out ``or the National Advisory Mental Health Council'' after ``appropriate entity of the Department''.

Subsec. (c). Pub. L. 99-660 added subsec. (c).

1985--Subsec. (a)(3). Pub. L. 99-158, Sec. 3(a)(5)(A), substituted ``as are recommended by the advisory council to the entity of the Department supporting such projects or, in the case of mental health projects, by the National Advisory Mental Health Council; and make, upon recommendation of the advisory council to the appropriate entity of the Department or the National Advisory Mental Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research'' for ``as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Cancer Advisory Board, or, with respect to mental health, recommended by the National Advisory Mental Health Council, or with respect to heart, blood vessel, lung, and blood diseases and blood resources, recommended by the National Heart, Lung, and Blood Advisory Council, or, with respect to dental diseases and conditions, recommended by the National Advisory Dental Research Council; and include in the grants for any such project grants of penicillin and other antibiotic compounds for use in such project; and make, upon recommendation of the National Advisory Health Council, grants-in-aid to public or nonprofit universities, hospitals, laboratories, and other institutions for the general support of their research: Provided, That such uniform percentage, not to exceed 15 per centum, as the Secretary may determine, of the amounts provided for grants for research projects for

any fiscal year through the appropriations for the National Institutes of Health may be transferred from such appropriations to a separate account to be available for such research grants-in-aid for such fiscal year''.

Subsec. (a)(8). Pub. L. 99-158, Sec. 3(a)(5)(B), substituted ``recommendations of the advisory councils to the appropriate entities of the Department or, with respect to mental health, the National Advisory Mental Health Council, such additional means as the Secretary considers'' for ``recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Cancer Advisory Board, or, with respect to mental health, upon recommendation of the National Advisory Mental Health Council, or, with respect to heart, blood vessel, lung, and blood diseases and blood resources, upon recommendation of the National Heart, Lung and Blood Advisory Council, or, with respect to dental diseases and conditions, upon recommendations of the National Advisory Dental Research Council, such additional means as he deems''.

1978--Pub. L. 95-622 designated existing provisions as subsec. (a), redesignated former pars. (a) to (h) as (1) to (8), respectively, substituted ``Secretary'' for ``Surgeon General'' wherever appearing, and inserted following par. (8) provisions relating to authority of Secretary to make available to individuals and entities substances and living organisms, and added subsec. (b).

1976--Subsecs. (c), (h). Pub. L. 94-278 substituted ``heart, blood vessel, lung, and blood diseases and blood resources'' for ``heart diseases'' and ``National Heart, Lung and Blood Advisory Council'' for ``National Heart and Lung Advisory Council''.

1974--Subsec. (c). Pub. L. 93-348, Sec. 104(a)(1), redesignated subsec. (d) as (c) and substituted ``research projects'' for ``research or research training projects'' in two places, ``general support of their research'' for ``general support of their research and research training programs'' and ``research grants-in-aid'' for ``research and research training program grants-in-aid''.

Former subsec. (c), authorizing Surgeon General to establish and maintain research fellowships in the Public Health Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad, was struck out.

Subsec. (d). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsec. (e) as (d). Pub. L. 93-282 substituted ``mental health, including research on the use and effect of alcohol and other psychoactive drugs'' for ``the use and effect of drugs'' in former concluding provisions of section 242a(a) of this title. See 1988 Amendment note above.

Subsecs. (e), (f). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsecs. (f) and (g) as (e) and (f), respectively. Former subsec. (e) redesignated (d).

Subsec. (g). Pub. L. 93-352 struck out ``during the fiscal year ending June 30, 1966, and each of the eight succeeding fiscal years'' after ``Enter into contracts''. Notwithstanding directory language that amendment be made to subsec. (h), the amendment was executed to subsec. (g) to reflect the probable intent of Congress and the intervening redesignation of subsec. (h) as (g) by Pub. L. 93-348.

Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsec. (h) as (g). Former subsec. (g) redesignated (f).

Subsecs. (h), (i). Pub. L. 93-348, Sec. 104(a)(1)(C), redesignated subsecs. (h) and (i) as (g) and (h), respectively.

1972--Subsecs. (d), (i). Pub. L. 92-423 substituted ``National Heart and Lung Advisory Council'' for ``National Advisory Heart Council''.

1971--Subsecs. (d), (i). Pub. L. 92-218 substituted ``National Cancer Advisory Board'' for ``National Advisory Cancer Council''.

1970--Subsec. (d). Pub. L. 91-513 added subsec. (d). See 1988 Amendment note above.

Subsec. (h). Pub. L. 91-515 substituted ``eight'' for ``five'' succeeding fiscal years.

1967--Subsec. (h). Pub. L. 90-174 substituted ``five'' for ``two'' succeeding fiscal years.

1965--Subsecs. (h), (i). Pub. L. 89-115 added subsec. (h) and redesignated former subsec. (h) as (i).

1962--Subsec. (d). Pub. L. 87-838 inserted ``or research training'' in two places.

1960--Subsec. (d). Pub. L. 86-798 authorized the Surgeon General, upon recommendation of the National Advisory Health Council, to make grants to public or non-profit universities, hospitals, laboratories, and other institutions to support research and research training programs, and to make available for such research and research training programs, up to 15 per centum of amounts

provided for research grants through the appropriations for the National Institutes of Health.

1956--Subsecs. (g), (h). Act July 3, 1956, added subsec. (g) and redesignated former subsec. (g) as (h).

1948--Subsec. (d). Acts June 16, 1948, Sec. 4(e), and June 24, 1948, Sec. 4(e), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

Subsec. (d). Act June 25, 1948, continued in basic legislation the authority to purchase penicillin and other antibiotic compounds for use in research projects.

Subsec. (g). Acts June 16, 1948, Sec. 4(f), and June 24, 1948, Sec. 4(f), made provisions applicable to the National Advisory Heart Council and the National Advisory Dental Research Council, respectively.

1946--Subsec. (d). Act July 3, 1946, made the National Advisory Mental Health Council the body to make recommendations to the Surgeon General on awarding of grants-in-aid for research projects with respect to mental health.

Subsec. (g). Act July 3, 1946, gave National Advisory Health Council the right to make recommendations to carry out purposes of this section.

Change of Name

``Secretary of Health and Human Services'' substituted for ``Secretary of Health, Education, and Welfare'' in subsec. (a)(7), and ``Department of Health and Human Services'' substituted for ``Department of Health, Education, and Welfare'' in subsec. (b)(1), (3), and (4)(D)(I), (II), pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

Effective Date of 1978 Amendment

Sections 261 and 262 of Pub. L. 95-622 provided that the amendments made by those sections are effective Oct. 1, 1978.

Effective Date of 1974 Amendment

Section 104(b) of Pub. L. 93-348 provided that: ``The amendments made by subsection (a) [amending this section and sections 242a, 282, 286a, 286b, 287a, 287b, 287d, 288a,

289c, 289c-1, 289g, 289k, and heading preceding section 289l of this title] shall not apply with respect to commitments made before the date of the enactment of this Act [July 12, 1974] by the Secretary of Health, Education, and Welfare for research training under the provisions of the Public Health Service Act amended or repealed by subsection (a).'

Effective Date of 1972 Amendment

Amendment by Pub. L. 92-423 effective 60 days after Sept. 19, 1972, or on such prior date after Sept. 19, 1972, as the President shall prescribe and publish in the Federal Register, see section 9 of Pub. L. 92-423, set out as a note under section 218 of this title.

Effective Date of 1971 Amendment

Amendment by Pub. L. 92-218 effective 60 days after Dec. 23, 1971, or on such prior date after Dec. 23, 1971, as the President shall prescribe and publish in the Federal Register, see section 7 of Pub. L. 92-218, set out as a note under section 218 of this title.

Coordination of Data Surveys and Reports

Pub. L. 106-113, div. B, Sec. 1000(a)(6) [title VII, Sec. 703(e)], Nov. 29, 1999, 113 Stat. 1536, 1501A-402, provided that: ``The Secretary of Health and Human Services, through the Assistant Secretary for Planning and Evaluation, shall establish a clearinghouse for the consolidation and coordination of all Federal databases and reports regarding children's health.'

Female Genital Mutilation

Pub. L. 104-134, title I, Sec. 101(d) [title V, Sec. 520], Apr. 26, 1996, 110 Stat. 1321-211, 1321-250; renumbered title I, Pub. L. 104-140, Sec. 1(a), May 2, 1996, 110 Stat. 1327, provided that:
``(a) Congress finds that--

((1) the practice of female genital mutilation is carried out by members of certain cultural and religious groups within the United States; and

((2) the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved.

((b) The Secretary of Health and Human Services shall do the following:

((1) Compile data on the number of females living in the United States who have been subjected to female genital mutilation (whether in the United States or in their countries of origin), including a specification of the number of girls under the age of 18 who have been subjected to such mutilation.

((2) Identify communities in the United States that practice female genital mutilation, and design and carry out outreach activities to educate individuals in the communities on the physical and psychological health effects of such practice. Such outreach activities shall be designed and implemented in collaboration with representatives of the ethnic groups practicing such mutilation and with representatives of organizations with expertise in preventing such practice.

((3) Develop recommendations for the education of students of schools of medicine and osteopathic medicine regarding female genital mutilation and complications arising from such mutilation.

Such recommendations shall be disseminated to such schools.

((c) For purposes of this section the term 'female genital mutilation' means the removal or infibulation (or both) of the whole or part of the clitoris, the labia minor, or the labia major.

((d) The Secretary of Health and Human Services shall commence carrying out this section not later than 90 days after the date of enactment of this Act [Apr. 26, 1996].''

Sentinel Disease Concept Study

Section 1910 of Pub. L. 103-43 directed Secretary of Health and Human Services, in cooperation with Agency for Toxic Substances and Disease Registry and Centers for Disease Control and Prevention, to design and implement a pilot sentinel disease surveillance system for identifying relationship between occupation of household members and incidence of subsequent conditions or diseases in other members of household, and required Director of the National Institutes of Health to prepare and submit to Congress, not later than 4 years after June 10, 1993, a report concerning this project.

Study of Thyroid Morbidity for Hanford, Washington

Section 161 of Pub. L. 100-607, as amended by Pub. L. 102-531, title III, Sec. 312(e)(1), Oct. 27, 1992, 106 Stat. 3506, directed Secretary of Health and Human Services, acting through Director of Centers for Disease Control and Prevention, to conduct a study of thyroid morbidity of the population, including Indian tribes and tribal organizations, in vicinity of Hanford, in State of Washington, authorized Director to contract out portions of study, and required Director, not later than 42 months after Nov. 4, 1988, to transmit a report, including such study, to Congress, chief executive officers of States of Oregon and Washington, and governing officials of Indian tribes in vicinity of Hanford, Washington.

National Commission on Sleep Disorders Research

Section 162 of Pub. L. 100-607 directed Secretary of Health and Human Services, after consultation with Director of National Institutes of Health, to establish a National Commission on Sleep Disorders Research to conduct a comprehensive study of present state of knowledge of incidence, prevalence, morbidity, and mortality resulting from sleep disorders, and of social and economic impact of such disorders, evaluate public and private facilities and resources (including trained personnel and research activities) available for diagnosis, prevention, and treatment of, and research into, such disorders, and

identify programs (including biological, physiological, behavioral, environmental, and social programs) by which improvement in management and research into sleep disorders could be accomplished and, not later than 18 months after initial meeting of Commission, to submit to appropriate Committees of Congress a final report, and provided for termination of the Commission 30 days after submission of final report.

Research With Respect to Health Resources and Services Administration

Section 632 of Pub. L. 100-607 provided that with respect to any program of research pursuant to this chapter, any such program carried out in fiscal year 1987 by an agency other than Health Resources and Services Administration (or appropriate to be carried out by such an agency) could not, for each of fiscal years 1989 through 1991, be carried out by such Administration.

Continuing Care for Psychiatric Patients in Former Clinical Research

Center at National Institute on Drug Abuse

Pub. L. 99-117, Sec. 10, Oct. 7, 1985, 99 Stat. 494, provided that:

``In any fiscal year beginning after September 30, 1981, from funds appropriated for carrying out section 301 of the Public Health Service Act [this section] with respect to mental health, the Secretary of Health and Human Services may provide, by contract or otherwise, for the continuing care of psychiatric patients who were under active and continuous treatment at the National Institute on Drug Abuse Clinical Research Center on the date such Clinical Research Center ceased operations.''

Analysis of Thyroid Cancer; Creation and Publication of Radioepidemiological Tables

Pub. L. 97-414, Sec. 7, Jan. 4, 1983, 96 Stat. 2059, provided that:

``(a) In carrying out section 301 of the Public Health Service Act [this section], the Secretary of Health and Human Services shall--

((1) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the risks of thyroid cancer that are associated with thyroid doses of Iodine 131;

((2) conduct scientific research and prepare analyses necessary to develop valid and credible methods to estimate the thyroid doses of Iodine 131 that are received by individuals from nuclear bomb fallout;

((3) conduct scientific research and prepare analyses necessary to develop valid and credible assessments of the exposure to Iodine

131 that the American people received from the Nevada atmospheric nuclear bomb tests; and

((4) prepare and transmit to the Congress within one year after the date of enactment of this Act [Jan. 4, 1983] a report with respect to the activities conducted in carrying out paragraphs (1), (2), and (3).

((b)(1) Within one year after the date of enactment of this Act

[Jan. 4, 1983], the Secretary of Health and Human Services shall devise and publish radioepidemiological tables that estimate the likelihood that persons who have or have had any of the radiation related cancers and who have received specific doses prior to the onset of such disease developed cancer as a result of these doses. These tables shall show a probability of causation of developing each radiation related cancer associated with receipt of doses ranging from 1 millirad to 1,000 rads in terms of sex, age at time of exposure, time from exposure to the onset of the cancer in question, and such other categories as the Secretary, after consulting with appropriate scientific experts, determines to be relevant. Each probability of causation shall be calculated and displayed as a single percentage figure.

((2) At the time the Secretary of Health and Human Services publishes the tables pursuant to paragraph (1), such Secretary shall also publish--

((A) for the tables of each radiation related cancer, an evaluation which will assess the credibility, validity, and degree of certainty associated with such tables; and

((B) a compilation of the formulas that yielded the probabilities of causation listed in such tables. Such formulas shall be published in such a manner and together with information necessary to determine the probability of causation of any individual who has or has had a radiation related cancer and has received any given dose.

``(3) The tables specified in paragraph (1) and the formulas specified in paragraph (2) shall be devised from the best available data that are most applicable to the United States, and shall be devised in accordance with the best available scientific procedures and expertise. The Secretary of Health and Human Services shall update these tables and formulas every four years, or whenever he deems it necessary to insure that they continue to represent the best available scientific data and expertise.''

Termination of Advisory Committees

Pub. L. 93-641, Sec. 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.