

§ 2617(c), Nov. 18, 1988, 102 Stat. 4240; Pub. L. 102-531, title III, § 312(d)(19), Oct. 27, 1992, 106 Stat. 3505; Pub. L. 103-43, title XX, § 2008(d)(4), June 10, 1993, 107 Stat. 212.)

Editorial Notes

AMENDMENTS

1993—Subsec. (d)(1). Pub. L. 103-43 substituted “AIDS Research Advisory Committee established under section 300cc-3 of this title” for “Clinical Research Review Committee”.

1992—Subsecs. (b)(1), (c)(1). Pub. L. 102-531 substituted “Centers for Disease Control and Prevention” for “Centers for Disease Control”.

1988—Subsec. (e). Pub. L. 100-690 substituted “data bank on clinical trials and treatments” for “data bank” in heading.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-690 effective immediately after enactment of Pub. L. 100-607, which was approved Nov. 4, 1988, see section 2600 of Pub. L. 100-690, set out as a note under section 242m of this title.

§ 300cc-18. Development of model protocols for clinical care of infected individuals

(a) In general

(1) The Secretary, acting through the Director of the National Institutes of Health and after consultation with the Director of the Agency for Healthcare Research and Quality, may make grants to public and nonprofit private entities for the establishment of projects to develop model protocols for the clinical care of individuals infected with the etiologic agent for acquired immune deficiency syndrome, including treatment and prevention of HIV infection and related conditions among women.

(2) The Secretary may not make a grant under paragraph (1) unless—

(A) the applicant for the grant is a provider of comprehensive primary care; or

(B) the applicant for the grant agrees, with respect to the project carried out pursuant to paragraph (1), to enter into a cooperative arrangement with an entity that is a provider of comprehensive primary care.

(b) Requirement of provision of certain services

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, with respect to patients participating in the project carried out with the grant, services provided pursuant to the grant will include—

(1) monitoring, in clinical laboratories, of the condition of such patients;

(2) clinical intervention for infection with the etiologic agent for acquired immune deficiency syndrome, including measures for the prevention of conditions arising from the infection;

(3) information and counseling on the availability of treatments for such infection approved by the Commissioner of Food and Drugs, on the availability of treatments for such infection not yet approved by the Commissioner, and on the reports issued by the AIDS Research Advisory Committee under section 300cc-3(c)(2)(B) of this title;

(4) support groups; and

(5) information on, and referrals to, entities providing appropriate social support services.

(c) Limitation on imposition of charges for services

The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees that, if the applicant will routinely impose a charge for providing services pursuant to the grant, the applicant will not impose the charge on any individual seeking such services who is unable to pay the charge.

(d) Evaluation and reports

(1) The Secretary may not make a grant under subsection (a) unless the applicant for the grant agrees, with respect to the project carried out pursuant to subsection (a), to submit to the Secretary—

(A) information sufficient to assist in the replication of the model protocol developed pursuant to the project; and

(B) such reports as the Secretary may require.

(2) The Secretary shall provide for evaluations of projects carried out pursuant to subsection (a) and shall annually submit to the Congress a report describing such projects. The report shall include the findings made as a result of such evaluations and may include any recommendations of the Secretary for appropriate administrative and legislative initiatives with respect to the program established in this section.

(e) 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 1989 through 1991, and such sums as may be necessary for each of the fiscal years 1994 through 1996.

(July 1, 1944, ch. 373, title XXIII, § 2318, as added Pub. L. 100-607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3073; amended Pub. L. 103-43, title XVIII, § 1811(4), title XX, § 2008(d)(5), June 10, 1993, 107 Stat. 199, 212; Pub. L. 106-129, § 2(b)(2), Dec. 6, 1999, 113 Stat. 1670.)

Editorial Notes

AMENDMENTS

1999—Subsec. (a)(1). Pub. L. 106-129 substituted “Director of the Agency for Healthcare Research and Quality” for “Administrator for Health Care Policy and Research”.

1993—Subsec. (a)(1). Pub. L. 103-43, § 1811(4)(A), inserted “, acting through the Director of the National Institutes of Health and after consultation with the Administrator for Health Care Policy and Research,” after “The Secretary” and “, including treatment and prevention of HIV infection and related conditions among women” after “syndrome”.

Subsec. (b)(3). Pub. L. 103-43, § 2008(d)(5), substituted “AIDS Research Advisory Committee” for “Clinical Research Review Committee”.

Subsec. (e). Pub. L. 103-43, § 1811(4)(B), inserted before period at end “, and such sums as may be necessary for each of the fiscal years 1994 through 1996”.

Statutory Notes and Related Subsidiaries

TERMINATION OF REPORTING REQUIREMENTS

For termination, effective May 15, 2000, of provisions in subsec. (d)(2) of this section relating to annual sub-

mission to Congress of reports describing projects carried out pursuant to subsec. (a) of this section, see section 3003 of Pub. L. 104-66, as amended, set out as a note under section 1113 of Title 31, Money and Finance, and page 94 of House Document No. 103-7.

§ 300cc-19. National blood resource education program

After consultation with the Director of the National Heart, Lung, and Blood Institute and the Commissioner of Food and Drugs, the Secretary shall establish a program of research and education regarding blood donations and transfusions to maintain and improve the safety of the blood supply. Education programs shall be directed at health professionals, patients, and the community to—

(1) in the case of the public and patients undergoing treatment—

(A) increase awareness that the process of donating blood is safe;

(B) promote the concept that blood donors are contributors to a national need to maintain an adequate and safe blood supply;

(C) encourage blood donors to donate more than once a year; and

(D) encourage repeat blood donors to recruit new donors;

(2) in the case of health professionals—

(A) improve knowledge, attitudes, and skills of health professionals in the appropriate use of blood and blood components;

(B) increase the awareness and understanding of health professionals regarding the risks versus benefits of blood transfusion; and

(C) encourage health professionals to consider alternatives to the administration of blood or blood components for their patients; and

(3) in the case of the community, increase coordination, communication, and collaboration among community, professional, industry, and government organizations regarding blood donation and transfusion issues.

(July 1, 1944, ch. 373, title XXIII, §2319, as added Pub. L. 100-607, title II, §201(4), Nov. 4, 1988, 102 Stat. 3074.)

§ 300cc-20. Additional authority with respect to research

(a) Data collection with respect to national prevalence

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may, through representative sampling and other appropriate methodologies, provide for the continuous collection of data on the incidence in the United States of cases of acquired immune deficiency syndrome and of cases of infection with the etiologic agent for such syndrome. The Secretary may carry out the program of data collection directly or through cooperative agreements and contracts with public and nonprofit private entities.

(2) The Secretary shall encourage each State to enter into a cooperative agreement or contract under paragraph (1) with the Secretary in order to facilitate the prompt collection of the

most recent accurate data on the incidence of cases described in such paragraph.

(3) The Secretary shall ensure that data collected under paragraph (1) includes data on the demographic characteristics of the population of individuals with cases described in paragraph (1), including data on specific subpopulations at risk of infection with the etiologic agent for acquired immune deficiency syndrome.

(4) In carrying out this subsection, the Secretary shall, for the purpose of assuring the utility of data collected under this section, request entities with expertise in the methodologies of data collection to provide, as soon as is practicable, assistance to the Secretary and to the States with respect to the development and utilization of uniform methodologies of data collection.

(5) The Secretary shall provide for the dissemination of data collected pursuant to this subsection. In carrying out this paragraph, the Secretary may publish such data as frequently as the Secretary determines to be appropriate with respect to the protection of the public health. The Secretary shall publish such data not less than once each year.

(b) Epidemiological and demographic data

(1) The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop an epidemiological data base and shall provide for long-term studies for the purposes of—

(A) collecting information on the demographic characteristics of the population of individuals infected with the etiologic agent for acquired immune deficiency syndrome and the natural history of such infection; and

(B) developing models demonstrating the long-term domestic and international patterns of the transmission of such etiologic agent.

(2) The Secretary may carry out paragraph (1) directly or through grants to, or cooperative agreements¹ or contracts with, public and nonprofit private entities, including Federal agencies.

(c) Long-term research

The Secretary may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting long-term research into treatments for acquired immune deficiency syndrome developed from knowledge of the genetic nature of the etiologic agent for such syndrome.

(d) Social sciences research

The Secretary, acting through the Director of the National Institute of Mental Health, may make grants to public and nonprofit private entities for the purpose of assisting grantees in conducting scientific research into the psychological and social sciences as such sciences relate to acquired immune deficiency syndrome.

(e) Authorization of appropriations

(1) For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each fiscal year.

¹ So in original.