

TITLE 42 - THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A - PUBLIC HEALTH SERVICE
SUBCHAPTER XXI - RESEARCH WITH RESPECT TO ACQUIRED IMMUNE DEFICIENCY SYNDROME
Part B - Research Authority

§ 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) of this section 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) of this section 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) of this section unless the applicant for the grant agrees, with respect to the project carried out pursuant to subsection (a) of this section, 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) of this section 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

NB: This unofficial compilation of the U.S. Code is current as of Jan. 5, 2009 (see <http://www.law.cornell.edu/uscode/uscprint.html>).

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.)

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”.

Termination of Reporting Requirements

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