(B) information contained in the data banks established in subsections (c) and (d).

(c) Data bank on research information

(1) After consultation with the Director of the Office of AIDS Research, the Director of the Centers for Disease Control and Prevention, and the National Library of Medicine, the Secretary shall establish a data bank of information on the results of research with respect to acquired immune deficiency syndrome conducted in the United States and other countries.

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. To the extent practicable, the Secretary shall make such information available to researchers, physicians, and other appropriate individuals, of countries other than the United States.

(d) Data bank on clinical trials and treatments

(1) After consultation with the Commissioner of Food and Drugs, the AIDS Research Advisory Committee established under section 300cc–3 of this title, and the Director of the Office of AIDS Research, the Secretary shall, in carrying out subsection (a), establish a data bank of information on clinical trials and treatments with respect to infection with the etiologic agent for acquired immune deficiency syndrome (hereafter in this section referred to as the ''Data Bank'').

(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems available to individuals infected with the etiologic agent for acquired immune deficiency syndrome, to other members of the public, to health care providers, and to researchers.

(e) Requirements with respect to data bank on clinical trials and treatments

The Data Bank shall include the following:

(1) A registry of clinical trials of experimental treatments for acquired immune deficiency syndrome and related illnesses conducted under regulations promulgated pursuant to section 355 of title 21 that provides a description of the purpose of each experimental drug protocol either with the consent of the protocol sponsor, or when a trial to test efficacy begins. Information provided shall include eligibility criteria and the location of trial sites, and must be forwarded to the Data Bank by the sponsor of the trial not later than 21 days after the approval by the Food and Drug Administration.

(2) Information pertaining to experimental treatments for acquired immune deficiency syndrome that may be available under a treatment investigational new drug application that has been submitted to the Food and Drug Administration pursuant to part 312 of title 21, Code of Federal Regulations. The Data Bank shall also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, of such experimental treatments, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatment.

(July 1, 1944, ch. 373, title XXIII, § 2317, as added Pub. L. 100–607, title II, § 201(4), Nov. 4, 1988, 102 Stat. 3071; amended Pub. L. 100–690, title II, § 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.)

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.

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.)

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.

§ 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