shall, after consultation with the National Commission on Acquired Immune Deficiency Syndrome, by regulation issue such conditions for treatment programs to obtain authorization from the Secretary to provide interim maintenance treatment as may be necessary to carry out the purpose described in such subsection. Such conditions shall include conditions for preventing the unauthorized use of methadone.

(2) Counseling on HIV disease

The regulations issued under paragraph (1) shall provide that an authorization described in such paragraph may not be issued to a treatment program unless the program provides to recipients of the treatment counseling on preventing exposure to and the transmission of HIV disease.

(3) Permission of relevant State as condition of authorization

The regulations issued under paragraph (1) shall provide that the Secretary may not provide an authorization described in such paragraph to any treatment program in a State unless the chief public health officer of the State has certified to the Secretary that—

- (A) such officer does not object to the provision of such authorizations to treatment programs in the State; and
- (B) the provision of interim maintenance services in the State will not reduce the capacity of comprehensive treatment programs in the State to admit individuals to the programs (relative to the date on which such officer so certifies).

(4) Date certain for issuance of regulations; failure of Secretary

The Secretary shall issue the final rule for purposes of the regulations required in paragraph (1), and such rule shall be effective, not later than the expiration of the 180-day period beginning on July 10, 1992. If the Secretary fails to meet the requirement of the preceding sentence, the proposed rule issued on March 2, 1989, with respect to part 291 of title 21, Code of Federal Regulations (docket numbered 88N-0444; 54 Fed. Reg. 8973 et seq.) is deemed to take effect as a final rule upon the expiration of such period, and the provisions of paragraph (3) of this subsection are deemed to be incorporated into such rule.

(d) Definitions

For purposes of this section:

- (1) The term "interim maintenance services" means the provision of methadone in a treatment program under the circumstances described in paragraphs (1) and (2) of subsection (a) of this section.
- (2) The term "HIV disease" means infection with the etiologic agent for acquired immune deficiency syndrome.
- (3) The term "treatment program" means a public or nonprofit private program of treatment for dependence on heroin or other morphine-like drugs.

(July 1, 1944, ch. 373, title XIX, §1976, as added Pub. L. 102-321, title II, §204, July 10, 1992, 106 Stat. 412.)

PRIOR PROVISIONS

A prior section 300y-11, act July 1, 1944, ch. 373, title XIX, §1932, as added Aug. 13, 1981, Pub. L. 97-35, title IX, §901, 95 Stat. 559; amended Jan. 4, 1983, Pub. L. 97-414, §8(v), 96 Stat. 2063, related to applicability of other provisions and promulgation of regulations, prior to repeal by Pub. L. 99-280, §5, Apr. 24, 1986, 100 Stat. 400. Sections 300y-21 to 300y-27 terminated Jan. 1, 1991,

Sections 300y-21 to 300y-27 terminated Jan. 1, 1991, pursuant to section 300y-27 and were omitted from the Code.

Section 300y-21, act July 1, 1944, ch. 373, title XIX, §1931, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3117, provided definitions for this part.

A prior section 1931 of act July 1, 1944, ch. 373, title XIX, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 559, provided criminal penalty for false statements and was classified to former section 300y–10 of this title, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Section 300y-22, act July 1, 1944, ch. 373, title XIX, §1932, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3117, authorized appropriations for this part.

A prior section 1932 of act July 1, 1944, ch. 373, title XIX, as added Aug. 13, 1981, Pub. L. 97–35, title IX, §901, 95 Stat. 559; amended Jan. 4, 1983, Pub. L. 97–414, §8(v), 96 Stat. 2063, related to applicability of other provisions and promulgation of regulations and was classified to former section 300y–11 of this title, prior to repeal by Pub. L. 99–280, §5, Apr. 24, 1986, 100 Stat. 400.

Section 300y-23, act July 1, 1944, ch. 373, title XIX, §1933, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3117, provided for allotments under this part.

Section 300y-24, act July 1, 1944, ch. 373, title XIX, §1934, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3118, provided for payments under allotments to States.

Section 300y-25, act July 1, 1944, ch. 373, title XIX, §1935, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3118, specified use of allotments.

Section 300y-26, act July 1, 1944, ch. 373, title XIX, §1936, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3119, provided for applications, requirements of the application, and description of activities.

Section 300y-27, act July 1, 1944, ch. 373, title XIX, §1937, as added Nov. 4, 1988, Pub. L. 100-607, title IV, §408(a), 102 Stat. 3120; amended Aug. 16, 1989, Pub. L. 101-93, §5(f)(1)(B), 103 Stat. 612, provided for termination of this part effective Jan. 1, 1991.

EFFECTIVE DATE

Section effective July 10, 1992, with programs making awards providing financial assistance in fiscal year 1993 and subsequent years effective for awards made on or after Oct. 1, 1992, see section 801(b), (d)(1) of Pub. L. 102–321, set out as an Effective Date of 1992 Amendment note under section 236 of this title.

SUBCHAPTER XVIII—ADOLESCENT FAMILY LIFE DEMONSTRATION PROJECTS

$\S 300z$. Findings and purposes

- (a) The Congress finds that—
- (1) in 1978, an estimated one million one hundred thousand teenagers became pregnant, more than five hundred thousand teenagers carried their babies to term, and over one-half of the babies born to such teenagers were born out of wedlock;
- (2) adolescents aged seventeen and younger accounted for more than one-half of the out of wedlock births to teenagers;
- (3) in a high proportion of cases, the pregnant adolescent is herself the product of an unmarried parenthood during adolescence and is continuing the pattern in her own lifestyle;

- (4) it is estimated that approximately 80 per centum of unmarried teenagers who carry their pregnancies to term live with their families before and during their pregnancy and remain with their families after the birth of the child:
- (5) pregnancy and childbirth among unmarried adolescents, particularly young adolescents, often results in severe adverse health, social, and economic consequences including: a higher percentage of pregnancy and childbirth complications; a higher incidence of low birth weight babies; a higher infant mortality and morbidity; a greater likelihood that an adolescent marriage will end in divorce; a decreased likelihood of completing schooling; and higher risks of unemployment and welfare dependency; and therefore, education, training, and job research services are important for adolescent parents;
- (6)(A) adoption is a positive option for unmarried pregnant adolescents who are unwilling or unable to care for their children since adoption is a means of providing permanent families for such children from available approved couples who are unable or have difficulty in conceiving or carrying children of their own to term; and
- (B) at present, only 4 per centum of unmarried pregnant adolescents who carry their babies to term enter into an adoption plan or arrange for their babies to be cared for by relatives or friends;
- (7) an unmarried adolescent who becomes pregnant once is likely to experience recurrent pregnancies and childbearing, with increased risks:
- (8)(A) the problems of adolescent premarital sexual relations, pregnancy, and parenthood are multiple and complex and are frequently associated with or are a cause of other troublesome situations in the family; and
- (B) such problems are best approached through a variety of integrated and essential services provided to adolescents and their families by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives:
- (9) a wide array of educational, health, and supportive services are not available to adolescents with such problems or to their families, or when available frequently are fragmented and thus are of limited effectiveness in discouraging adolescent premarital sexual relations and the consequences of such relations;
- (10)(A) prevention of adolescent sexual activity and adolescent pregnancy depends primarily upon developing strong family values and close family ties, and since the family is the basic social unit in which the values and attitudes of adolescents concerning sexuality and pregnancy are formed, programs designed to deal with issues of sexuality and pregnancy will be successful to the extent that such programs encourage and sustain the role of the family in dealing with adolescent sexual activity and adolescent pregnancy;
- (B) Federal policy therefore should encourage the development of appropriate health,

- educational, and social services where such services are now lacking or inadequate, and the better coordination of existing services where they are available; and
- (C) services encouraged by the Federal Government should promote the involvement of parents with their adolescent children, and should emphasize the provision of support by other family members, religious and charitable organizations, voluntary associations, and other groups in the private sector in order to help adolescents and their families deal with complex issues of adolescent premarital sexual relations and the consequences of such relations; and
- (11)(A) there has been limited research concerning the societal causes and consequences of adolescent pregnancy;
- (B) there is limited knowledge concerning which means of intervention are effective in mediating or eliminating adolescent premarital sexual relations and adolescent pregnancy; and
- (C) it is necessary to expand and strengthen such knowledge in order to develop an array of approaches to solving the problems of adolescent premarital sexual relations and adolescent pregnancy in both urban and rural settings.
- (b) Therefore, the purposes of this subchapter are—
- (1) to find effective means, within the context of the family, of reaching adolescents before they become sexually active in order to maximize the guidance and support available to adolescents from parents and other family members, and to promote self discipline and other prudent approaches to the problem of adolescent premarital sexual relations, including adolescent pregnancy;
- (2) to promote adoption as an alternative for adolescent parents;
- (3) to establish innovative, comprehensive, and integrated approaches to the delivery of care services both for pregnant adolescents, with primary emphasis on unmarried adolescents who are seventeen years of age or under, and for adolescent parents, which shall be based upon an assessment of existing programs and, where appropriate, upon efforts to establish better coordination, integration, and linkages among such existing programs in order to—
 - (A) enable pregnant adolescents to obtain proper care and assist pregnant adolescents and adolescent parents to become productive independent contributors to family and community life; and
 - (B) assist families of adolescents to understand and resolve the societal causes which are associated with adolescent pregnancy;
- (4) to encourage and support research projects and demonstration projects concerning the societal causes and consequences of adolescent premarital sexual relations, contraceptive use, pregnancy, and child rearing;
- (5) to support evaluative research to identify effective services which alleviate, eliminate, or resolve any negative consequences of adolescent premarital sexual relations and adoles-

cent childbearing for the parents, the child, and their families; and

(6) to encourage and provide for the dissemination of results, findings, and information from programs and research projects relating to adolescent premarital sexual relations, pregnancy, and parenthood.

(July 1, 1944, ch. 373, title XX, \$2001, as added Pub. L. 97–35, title IX, \$955(a), Aug. 13, 1981, 95 Stat. 578; amended Pub. L. 98–512, \$2(b), (c), Oct. 19, 1984, 98 Stat. 2409.)

AMENDMENTS

1984—Subsec. (a)(5). Pub. L. 98-512, §2(b), struck out reference relating to developmental disabilities and inserted provision relating to importance of education, training, and job research services for adolescent parents.

Subsec. (b)(3). Pub. L. 98-512, $\S2(c)$, inserted "both" before "for pregnant adolescents".

§ 300z-1. Definitions; regulations applicable

- (a) For the purposes of this subchapter, the term—
 - (1) "Secretary" means the Secretary of Health and Human Services;
 - (2) "eligible person" means—
 - (A) with regard to the provision of care services, a pregnant adolescent, an adolescent parent, or the family of a pregnant adolescent or an adolescent parent; or
 - (B) with regard to the provision of prevention services and referral to such other services which may be appropriate, a nonpregnant adolescent:
 - (3) "eligible grant recipient" means a public or nonprofit private organization or agency which demonstrates, to the satisfaction of the Secretary—
 - (A) in the case of an organization which will provide care services, the capability of providing all core services in a single setting or the capability of creating a network through which all core services would be provided; or
 - (B) in the case of an organization which will provide prevention services, the capability of providing such services;
- (4) "necessary services" means services which may be provided by grantees which are—
 - (A) pregnancy testing and maternity counseling;
 - (B) adoption counseling and referral services which present adoption as an option for pregnant adolescents, including referral to licensed adoption agencies in the community if the eligible grant recipient is not a licensed adoption agency;
 - (C) primary and preventive health services including prenatal and postnatal care;
 - (D) nutrition information and counseling;
 - (E) referral for screening and treatment of venereal disease;
 - (F) referral to appropriate pediatric care;
 - (G) educational services relating to family life and problems associated with adolescent premarital sexual relations, including—
 - (i) information about adoption;
 - (ii) education on the responsibilities of sexuality and parenting;

- (iii) the development of material to support the role of parents as the provider of sex education; and
- (iv) assistance to parents, schools, youth agencies, and health providers to educate adolescents and preadolescents concerning self-discipline and responsibility in human sexuality;
- (H) appropriate educational and vocational services;
- (I) referral to licensed residential care or maternity home services; and
- (J) mental health services and referral to mental health services and to other appropriate physical health services;
- (K) child care sufficient to enable the adolescent parent to continue education or to enter into employment;
 - (L) consumer education and homemaking;
- (M) counseling for the immediate and extended family members of the eligible person:
 - (N) transportation;
- (O) outreach services to families of adolescents to discourage sexual relations among unemancipated minors:
 - (P) family planning services; and
- (Q) such other services consistent with the purposes of this subchapter as the Secretary may approve in accordance with regulations promulgated by the Secretary;
- (5) "core services" means those services which shall be provided by a grantee, as determined by the Secretary by regulation;
- (6) "supplemental services" means those services which may be provided by a grantee, as determined by the Secretary by regulation;
- (7) "care services" means necessary services for the provision of care to pregnant adolescents and adolescent parents and includes all core services with respect to the provision of such care prescribed by the Secretary by regulation:
- (8) "prevention services" means necessary services to prevent adolescent sexual relations, including the services described in subparagraphs (A), (D), (E), (G), (H), (M), (N), (O), and (Q) of paragraph (4):
- and (Q) of paragraph (4);
 (9) "adolescent" means an individual under the age of nineteen; and
- (10) "unemancipated minor" means a minor who is subject to the control, authority, and supervision of his or her parents or guardians, as determined under State law.
- (b) Until such time as the Secretary promulgates regulations pursuant to the second sentence of this subsection, the Secretary shall use the regulations promulgated under title VI of the Health Services and Centers Amendments of 1978 [42 U.S.C. 300a-21 et seq.] which were in effect on August 13, 1981, to determine which necessary services are core services for purposes of this subchapter. The Secretary may promulgate regulations to determine which necessary services are core services for purposes of this subchapter based upon an evaluation of and information concerning which necessary services are essential to carry out the purposes of this subchapter and taking into account (1) factors such as whether services are to be provided in urban

or rural areas, the ethnic groups to be served, and the nature of the populations to be served, and (2) the results of the evaluations required under section 300z-5(b) of this title. The Secretary may from time to time revise such regulations

(July 1, 1944, ch. 373, title XX, \$2002, as added Pub. L. 97–35, title IX, \$955(a), Aug. 13, 1981, 95 Stat. 580; amended Pub. L. 98–512, \$2(d), Oct. 19, 1984, 98 Stat. 2409.)

REFERENCES IN TEXT

The Health Services and Centers Amendments of 1978, referred to in subsec. (b), is Pub. L. 95–626, Nov. 10, 1978, 92 Stat. 3551, as amended. Title VI of the Health Services and Centers Amendments of 1978 was classified generally to part A (§300a–21 et seq.) of subchapter VIII–A of this chapter prior to its repeal by Pub. L. 97–35, title IX, §955(b), title XXI, §2193(f), Aug. 13, 1981, 95 Stat. 592, 828. For complete classification of this Act to the Code, see Short Title of 1978 Amendments note set out under section 201 of this title and Tables.

AMENDMENTS

1984—Subsec. (a)(4)(H). Pub. L. 98–512 struck out ''and referral to such services'' after ''vocational services''.

§ 300z-2. Demonstration projects; grant authorization, etc.

- (a) The Secretary may make grants to further the purposes of this subchapter to eligible grant recipients which have submitted an application which the Secretary finds meets the requirements of section 300z-5 of this title for demonstration projects which the Secretary determines will help communities provide appropriate care and prevention services in easily accessible locations. Demonstration projects shall, as appropriate, provide, supplement, or improve the quality of such services. Demonstration projects shall use such methods as will strengthen the capacity of families to deal with the sexual behavior, pregnancy, or parenthood of adolescents and to make use of support systems such as other family members, friends, religious and charitable organizations, and voluntary associations.
- (b) Grants under this subchapter for demonstration projects may be for the provision of—
 - (1) care services;
 - (2) prevention services; or
 - (3) a combination of care services and prevention services.

(July 1, 1944, ch. 373, title XX, §2003, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 582.)

§ 300z-3. Uses of grants for demonstration projects for services

(a) Covered projects

Except as provided in subsection (b) of this section, funds provided for demonstration projects for services under this subchapter may be used by grantees only to—

- (1) provide to eligible persons—
 - (A) care services;
 - (B) prevention services; or
- (C) care and prevention services (in the case of a grantee who is providing a combination of care and prevention services);

- (2) coordinate, integrate, and provide linkages among providers of care, prevention, and other services for eligible persons in furtherance of the purposes of this subchapter;
- (3) provide supplemental services where such services are not adequate or not available to eligible persons in the community and which are essential to the care of pregnant adolescents and to the prevention of adolescent premarital sexual relations and adolescent pregnancy:
- (4) plan for the administration and coordination of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents which will further the objectives of this subchapter; and
- (5) fulfill assurances required for grant approval by section 300z-5 of this title.

(b) Family planning services; availability in community

- (1) No funds provided for a demonstration project for services under this subchapter may be used for the provision of family planning services (other than counseling and referral services) to adolescents unless appropriate family planning services are not otherwise available in the community.
- (2) Any grantee who receives funds for a demonstration project for services under this subchapter and who, after determining under paragraph (1) that appropriate family planning services are not otherwise available in the community, provides family planning services (other than counseling and referral services) to adolescents may only use funds provided under this subchapter for such family planning services if all funds received by such grantee from all other sources to support such family planning services are insufficient to support such family planning services.

(c) Fees for services: criteria

Grantees who receive funds for a demonstration project for services under this subchapter shall charge fees for services pursuant to a fee schedule approved by the Secretary as a part of the application described in section 300z-5 of this title which bases fees charged by the grantee on the income of the eligible person or the parents or legal guardians of the eligible person and takes into account the difficulty adolescents face in obtaining resources to pay for services. A grantee who receives funds for a demonstration project for services under this subchapter may not, in any case, discriminate with regard to the provision of services to any individual because of that individual's inability to provide payment for such services, except that in determining the ability of an unemancipated minor to provide payment for services, the income of the family of an unemancipated minor shall be considered in determining the ability of such minor to make such payments unless the parents or guardians of the unemancipated minor refuse to make such payments.

(July 1, 1944, ch. 373, title XX, \$2004, as added Pub. L. 97–35, title IX, \$955(a), Aug. 13, 1981, 95 Stat. 583.)

§ 300z-4. Grants for demonstration projects for services

(a) Priorities

In approving applications for grants for demonstration projects for services under this subchapter, the Secretary shall give priority to applicants who—

- (1) serve an area where there is a high incidence of adolescent pregnancy;
- (2) serve an area with a high proportion of low-income families and where the availability of programs of care for pregnant adolescents and adolescent parents is low:
 - (3) show evidence—
 - (A) in the case of an applicant who will provide care services, of having the ability to bring together a wide range of needed core services and, as appropriate, supplemental services in comprehensive single-site projects, or to establish a well-integrated network of such services (appropriate for the target population and geographic area to be served including the special needs of rural areas) for pregnant adolescents or adolescent parents; or
 - (B) in the case of an applicant who will provide prevention services, of having the ability to provide prevention services for adolescents and their families which are appropriate for the target population and the geographic area to be served, including the special needs of rural areas:
- (4) will utilize to the maximum extent feasible existing available programs and facilities such as neighborhood and primary health care centers, maternity homes which provide or can be equipped to provide services to pregnant adolescents, agencies serving families. youth, and children with established programs of service to pregnant adolescents and vulnerable families, licensed adoption agencies, children and youth centers, maternal and infant health centers, regional rural health facilities, school and other educational programs, mental health programs, nutrition programs, recreation programs, and other ongoing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents;
- (5) make use, to the maximum extent feasible, of other Federal, State, and local funds, programs, contributions, and other third-party reimbursements;
- (6) can demonstrate a community commitment to the program by making available to the demonstration project non-Federal funds, personnel, and facilities;
- (7) have involved the community to be served, including public and private agencies, adolescents, and families, in the planning and implementation of the demonstration project; and
- (8) will demonstrate innovative and effective approaches in addressing the problems of adolescent premarital sexual relations, pregnancy, or parenthood, including approaches to provide pregnant adolescents with adequate information about adoption.

(b) Factors to be considered in making grants; special needs of rural areas

- (1) The amount of a grant for a demonstration project for services under this subchapter shall be determined by the Secretary, based on factors such as the incidence of adolescent pregnancy in the geographic area to be served, and the adequacy of pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents in such area.
- (2) In making grants for demonstration projects for services under this subchapter, the Secretary shall consider the special needs of rural areas and, to the maximum extent practicable, shall distribute funds taking into consideration the relative number of adolescents in such areas in need of such services.

(c) Duration; Federal share

- (1) A grantee may not receive funds for a demonstration project for services under this subchapter for a period in excess of 5 years.
- (2)(A) Subject to paragraph (3), a grant for a demonstration project for services under this subchapter may not exceed—
 - (i) 70 per centum of the costs of the project for the first and second years of the project;
 - (ii) 60 per centum of such costs for the third year of the project;
 - (iii) 50 per centum of such costs for the fourth year of the project; and
 - (iv) 40 per centum of such costs for the fifth year of the project.
- (B) Non-Federal contributions required by subparagraph (A) may be in cash or in kind, fairly evaluated, including plant, equipment, or services.
- (3) The Secretary may waive the limitation specified in paragraph (2)(A) for any year in accordance with criteria established by regulation.
- (July 1, 1944, ch. 373, title XX, §2005, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 584.)

§ 300z-5. Requirements for applications

(a) Form, content, and assurances

An application for a grant for a demonstration project for services under this subchapter shall be in such form and contain such information as the Secretary may require, and shall include—

- (1) an identification of the incidence of adolescent pregnancy and related problems:
- (2) a description of the economic conditions and income levels in the geographic area to be served:
- (3) a description of existing pregnancy prevention services and programs of care for pregnant adolescents and adolescent parents (including adoption services), and including where, how, by whom, and to which population groups such services are provided, and the extent to which they are coordinated in the geographic area to be served;
- (4) a description of the major unmet needs for services for adolescents at risk of initial or recurrent pregnancies and an estimate of the number of adolescents not being served in the area.
- (5)(A) in the case of an applicant who will provide care services, a description of how all

core services will be provided in the demonstration project using funds under this subchapter or will otherwise be provided by the grantee in the area to be served, the population to which such services will be provided, how such services will be coordinated, integrated, and linked with other related programs and services and the source or sources of funding of such core services in the public and private sectors; or

(B) in the case of an applicant who will provide prevention services, a description of the necessary services to be provided and how the applicant will provide such services;

- (6) a description of the manner in which adolescents needing services other than the services provided directly by the applicant will be identified and how access and appropriate referral to such other services (such as medicaid; licensed adoption agencies; maternity home services; public assistance; employment services; child care services for adolescent parents; and other city, county, and State programs related to adolescent pregnancy) will be provided, including a description of a plan to coordinate such other services with the services supported under this subchapter;
- (7) a description of the applicant's capacity to continue services as Federal funds decrease and in the absence of Federal assistance;
- (8) a description of the results expected from the provision of services, and the procedures to be used for evaluating those results;
- (9) a summary of the views of public agencies, providers of services, and the general public in the geographic area to be served, concerning the proposed use of funds provided for a demonstration project for services under this subchapter and a description of procedures used to obtain those views, and, in the case of applicants who propose to coordinate services administered by a State, the written comments of the appropriate State officials responsible for such services;
- (10) assurances that the applicant will have an ongoing quality assurance program;
- (11) assurances that, where appropriate, the applicant shall have a system for maintaining the confidentiality of patient records in accordance with regulations promulgated by the Secretary:
- (12) assurances that the applicant will demonstrate its financial responsibility by the use of such accounting procedures and other requirements as may be prescribed by the Secretary:
- (13) assurances that the applicant (A) has or will have a contractual or other arrangement with the agency of the State (in which the applicant provides services) that administers or supervises the administration of a State plan approved under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] for the payment of all or a part of the applicant's costs in providing health services to persons who are eligible for medical assistance under such a State plan, or (B) has made or will make every reasonable effort to enter into such an arrangement;
- (14) assurances that the applicant has made or will make and will continue to make every

reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to benefits under title V of the Social Security Act [42 U.S.C. 701 et seq.], to medical assistance under a State plan approved under title XIX of such Act [42 U.S.C. 1396 et seq.], or to assistance for medical expenses under any other public assistance program or private health insurance program;

(15) assurances that the applicant has or will make and will continue to make every reasonable effort to collect appropriate reimbursement for its costs in providing services to persons entitled to services under parts B and E of title IV [42 U.S.C. 620 et seq., 670 et seq.] and title XX of the Social Security Act [42 U.S.C. 1397 et seq.];

(16)(A) a description of—

- (i) the schedule of fees to be used in the provision of services, which shall comply with section 300z-3(c) of this title and which shall be designed to cover all reasonable direct and indirect costs incurred by the applicant in providing services; and
- (ii) a corresponding schedule of discounts to be applied to the payment of such fees, which shall comply with section 300z-3(c) of this title and which shall be adjusted on the basis of the ability of the eligible person to pay;
- (B) assurances that the applicant has made and will continue to make every reasonable effort—
 - (i) to secure from eligible persons payment for services in accordance with such schedules;
 - (ii) to collect reimbursement for health or other services provided to persons who are entitled to have payment made on their behalf for such services under any Federal or other government program or private insurance program; and
 - (iii) to seek such reimbursement on the basis of the full amount of fees for services without application of any discount; and
- (C) assurances that the applicant has submitted or will submit to the Secretary such reports as the Secretary may require to determine compliance with this paragraph;
- (17) assurances that the applicant will make maximum use of funds available under subchapter VIII of this chapter;
- (18) assurances that the acceptance by any individual of family planning services or family planning information (including educational materials) provided through financial assistance under this subchapter shall be voluntary and shall not be a prerequisite to eligibility for or receipt of any other service furnished by the applicant;
- (19) assurances that fees collected by the applicant for services rendered in accordance with this subchapter shall be used by the applicant to further the purposes of this subchapter;
- (20) assurances that the applicant, if providing both prevention and care services will not exclude or discriminate against any adolescent who receives prevention services and sub-

sequently requires care services as a pregnant adolescent;

- (21) a description of how the applicant will, as appropriate in the provision of services—
 - (A) involve families of adolescents in a manner which will maximize the role of the family in the solution of problems relating to the parenthood or pregnancy of the adolescent;
 - (B) involve religious and charitable organizations, voluntary associations, and other groups in the private sector as well as services provided by publicly sponsored initiatives:

(22)(A) assurances that—

- (i) except as provided in subparagraph (B) and subject to clause (ii), the applicant will notify the parents or guardians of any unemancipated minor requesting services from the applicant and, except as provided in subparagraph (C), will obtain the permission of such parents or guardians with respect to the provision of such services; and
- (ii) in the case of a pregnant unemancipated minor requesting services from the applicant, the applicant will notify the parents or guardians of such minor under clause (i) within a reasonable period of time;
- (B) assurances that the applicant will not notify or request the permission of the parents or guardian of any unemancipated minor without the consent of the minor—
- (i) who solely is requesting from the applicant pregnancy testing or testing or treatment for venereal disease:
- (ii) who is the victim of incest involving a parent; or
- (iii) if an adult sibling of the minor or an adult aunt, uncle, or grandparent who is related to the minor by blood certifies to the grantee that notification of the parents or guardians of such minor would result in physical injury to such minor; and
- (C) assurances that the applicant will not require, with respect to the provision of services, the permission of the parents or guardians of any pregnant unemancipated minor if such parents or guardians are attempting to compel such minor to have an abortion;
- (23) assurances that primary emphasis for services supported under this subchapter shall be given to adolescents seventeen and under who are not able to obtain needed assistance through other means;
- (24) assurances that funds received under this subchapter shall supplement and not supplant funds received from any other Federal, State, or local program or any private sources of funds; and
- (25) a plan for the conduct of, and assurances that the applicant will conduct, evaluations of the effectiveness of the services supported under this subchapter in accordance with subsection (b) of this section.

(b) Evaluations: amount, conduct, and technical assistance

(1) Each grantee which receives funds for a demonstration project for services under this subchapter shall expend at least 1 per centum but not in excess of 5 per centum of the amounts received under this subchapter for the conduct of evaluations of the services supported under this subchapter. The Secretary may, for a particular grantee upon good cause shown, waive the provisions of the preceding sentence with respect to the amounts to be expended on evaluations, but may not waive the requirement that such evaluations be conducted.

(2) Evaluations required by paragraph (1) shall be conducted by an organization or entity which is independent of the grantee providing services supported under this subchapter. To assist in conducting the evaluations required by paragraph (1), each grantee shall develop a working relationship with a college or university located in the grantee's State which will provide or assist in providing monitoring and evaluation of services supported under this subchapter unless no college or university in the grantee's State is willing or has the capacity to provide or assist in providing such monitoring and assistance.

(3) The Secretary may provide technical assistance with respect to the conduct of evaluations required under this subsection to any grantee which is unable to develop a working relationship with a college or university in the applicant's State for the reasons described in paragraph (2).

(c) Reports

Each grantee which receives funds for a demonstration project for services under this subchapter shall make such reports concerning its use of Federal funds as the Secretary may require. Reports shall include, at such times as are considered appropriate by the Secretary, the results of the evaluations of the services supported under this subchapter.

(d) Notification of parents; "adult" defined

- (1) A grantee shall periodically notify the Secretary of the exact number of instances in which a grantee does not notify the parents or guardians of a pregnant unemancipated minor under subsection (a)(22)(B)(iii) of this section.
- (2) For purposes of subsection (a)(22)(B)(iii) of this section, the term "adult" means an adult as defined by State law.

(e) Submission of applications to Governor; comments by Governor

Each applicant shall provide the Governor of the State in which the applicant is located a copy of each application submitted to the Secretary for a grant for a demonstration project for services under this subchapter. The Governor shall submit to the applicant comments on any such application within the period of sixty days beginning on the day when the Governor receives such copy. The applicant shall include the comments of the Governor with such application.

(f) Availability of core services

No application submitted for a grant for a demonstration project for care services under this subchapter may be approved unless the Secretary is satisfied that core services shall be available through the applicant within a reasonable time after such grant is received.

(July 1, 1944, ch. 373, title XX, \$2006, as added Pub. L. 97–35, title IX, \$955(a), Aug. 13, 1981, 95 Stat. 585.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsec. (a)(13) to (15), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Parts B and E of title IV of the Social Security Act are classified generally to part B (§620 et seq.) and part E (§670 et seq.) of subchapter IV of chapter 7 of this title. Titles V, XIX, and XX of the Social Security Act are classified generally to subchapters V (§701 et seq.), XIX (§1396 et seq.), and XX (§1397 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

§ 300z-6. Coordination of programs

- (a) The Secretary shall coordinate Federal policies and programs providing services relating to the prevention of adolescent sexual relations and initial and recurrent adolescent pregnancies and providing care services for pregnant adolescents. In achieving such coordination, the Secretary shall—
 - (1) require grantees who receive funds for demonstration projects for services under this subchapter to report periodically to the Secretary concerning Federal, State, and local policies and programs that interfere with the delivery of and coordination of pregnancy prevention services and other programs of care for pregnant adolescents and adolescent parents:
 - (2) provide technical assistance to facilitate coordination by State and local recipients of Federal assistance:
 - (3) review all programs administered by the Department of Health and Human Services which provide prevention services or care services to determine if the policies of such programs are consistent with the policies of this subchapter, consult with other departments and agencies of the Federal Government who administer programs that provide such services, and encourage such other departments and agencies to make recommendations, as appropriate, for legislation to modify such programs in order to facilitate the use of all Government programs which provide such services as a basis for delivery of more comprehensive prevention services and more comprehensive programs of care for pregnant adolescents and adolescent parents;
 - (4) give priority in the provision of funds, where appropriate, to applicants using single or coordinated grant applications for multiple programs; and
 - (5) give priority, where appropriate, to the provision of funds under Federal programs administered by the Secretary (other than the program established by this subchapter) to projects providing comprehensive prevention services and comprehensive programs of care for pregnant adolescents and adolescent parents.
- (b) Any recipient of a grant for a demonstration project for services under this subchapter shall coordinate its activities with any other recipient of such a grant which is located in the same locality.
- (July 1, 1944, ch. 373, title XX, \$2007, as added Pub. L. 97–35, title IX, \$955(a), Aug. 13, 1981, 95 Stat. 589.)

§ 300z-7. Research

(a) Grants and contracts; duration; renewal; amount

- (1) The Secretary may make grants and enter into contracts with public agencies or private organizations or institutions of higher education to support the research and dissemination activities described in paragraphs (4), (5), and (6) of section 300z(b) of this title.
- (2) The Secretary may make grants or enter into contracts under this section for a period of one year. A grant or contract under this section for a project may be renewed for four additional one-year periods, which need not be consecutive.
- (3) A grant or contract for any one-year period under this section may not exceed \$100,000 for the direct costs of conducting research or disemination¹ activities under this section and may include such additional amounts for the indirect costs of conducting such activities as the Secretary determines appropriate. The Secretary may waive the preceding sentence with respect to a specific project if he determines that—
 - (A) exceptional circumstances warrant such waiver and that the project will have national impact; or
 - (B) additional amounts are necessary for the direct costs of conducting limited demonstration projects for the provision of necessary services in order to provide data for research carried out under this subchapter.
- (4) The amount of any grant or contract made under this section may remain available for obligation or expenditure after the close of the one-year period for which such grant or contract is made in order to assist the recipient in preparing the report required by subsection (f)(1) of this section.

(b) Scope of permissible activities

- (1) Funds provided for research under this section may be used for descriptive or explanatory surveys, longitudinal studies, or limited demonstration projects for services that are for the purpose of increasing knowledge and understanding of the matters described in paragraphs (4) and (5) of section 300z(b) of this title.
- (2) Funds provided under this section may not be used for the purchase or improvement of land, or the purchase, construction, or permanent improvement (other than minor remodeling) of any building or facility.

(c) Applications

The Secretary may not make any grant or enter into any contract to support research or dissemination activities under this section unless—

- (1) the Secretary has received an application for such grant or contract which is in such form and which contains such information as the Secretary may by regulation require;
- (2) the applicant has demonstrated that the applicant is capable of conducting one or more of the types of research or dissemination activities described in paragraph (4), (5), or (6) of section 300z(b) of this title; and

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

(3) in the case of an application for a research project, the panel established by subsection (e)(2) of this section has determined that the project is of scientific merit.

(d) Coordination with National Institutes of Health

The Secretary shall, where appropriate, coordinate research and dissemination activities carried out under this section with research and dissemination activities carried out by the National Institutes of Health.

(e) Review of applications for grants and contracts; establishment of review panel

- (1) The Secretary shall establish a system for the review of applications for grants and contracts under this section. Such system shall be substantially similar to the system for scientific peer review of the National Institutes of Health and shall meet the requirements of paragraphs (2) and (3).
- (2) In establishing the system required by paragraph (1), the Secretary shall establish a panel to review applications under this section. Not more than 25 per centum of the members of the panel shall be physicians. The panel shall meet as often as may be necessary to facilitate the expeditious review of applications under this section, but not less than once each year. The panel shall review each project for which an application is made under this section, evaluate the scientific merit of the project, determine whether the project is of scientific merit, and make recommendations to the Secretary concerning whether the application for the project should be approved.
- (3) The Secretary shall make grants under this section from among the projects which the panel established by paragraph (2) has determined to be of scientific merit and may only approve an application for a project if the panel has made such determination with respect to such a project. The Secretary shall make a determination with respect to an application within one month after receiving the determinations and recommendations of such panel with respect to the application.

(f) Reports

- (1)(A) The recipient of a grant or contract for a research project under this section shall prepare and transmit to the Secretary a report describing the results and conclusions of such research. Except as provided in subparagraph (B), such report shall be transmitted to the Secretary not later than eighteen months after the end of the year for which funds are provided under this section. The recipient may utilize reprints of articles published or accepted for publication in professional journals to supplement or replace such report if the research contained in such articles was supported under this section during the year for which the report is required.
- (B) In the case of any research project for which assistance is provided under this section for two or more consecutive one-year periods, the recipient of such assistance shall prepare and transmit the report required by subparagraph (A) to the Secretary not later than twelve months after the end of each one-year period for which such funding is provided.

(2) Recipients of grants and contracts for dissemination under this section shall submit to the Secretary such reports as the Secretary determines appropriate.

(July 1, 1944, ch. 373, title XX, §2008, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 589; amended Pub. L. 98–512, §2(e), Oct. 19, 1984, 98 Stat. 2409.)

AMENDMENTS

1984—Subsec. (g). Pub. L. 98–512 struck out subsec. (g) which provided for collection of survey data used primarily for generation of national population estimates.

§ 300z-8. Evaluation and administration

- (a) Of the funds appropriated under this subchapter, the Secretary shall reserve not less than 1 per centum and not more than 3 per centum for the evaluation of activities carried out under this subchapter. The Secretary shall submit to the appropriate committees of the Congress a summary of each evaluation conducted under this section.
- (b) The officer or employee of the Department of Health and Human Services designated by the Secretary to carry out the provisions of this subchapter shall report directly to the Assistant Secretary for Health with respect to the activities of such officer or employee in carrying out such provisions.

(July 1, 1944, ch. 373, title XX, §2009, as added Pub. L. 97-35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 591.)

§ 300z-9. Authorization of appropriations

- (a) For the purpose of carrying out this subchapter, there are authorized to be appropriated \$30,000,000 for the fiscal year ending September 30, 1982, \$30,000,000 for the fiscal year ending September 30, 1983, \$30,000,000 for the fiscal year ending September 30, 1984, and \$30,000,000 for the fiscal year ending September 30, 1985.
- (b) At least two-thirds of the amounts appropriated to carry out this subchapter shall be used to make grants for demonstration projects for services
- (c) Not more than one-third of the amounts specified under subsection (b) of this section for use for grants for demonstration projects for services shall be used for grants for demonstration projects for prevention services.

(July 1, 1944, ch. 373, title XX, §2010, as added Pub. L. 97–35, title IX, §955(a), Aug. 13, 1981, 95 Stat. 591; amended Pub. L. 98–512, §2(a), Oct. 19, 1984, 98 Stat. 2409.)

AMENDMENTS

1984—Subsec. (a). Pub. L. 98-509 inserted provisions authorizing appropriations for fiscal year ending Sept. 30, 1985.

§ 300z-10. Restrictions

(a) Grants or payments may be made only to programs or projects which do not provide abortions or abortion counseling or referral, or which do not subcontract with or make any payment to any person who provides abortions or abortion counseling or referral, except that any such program or project may provide referral for

abortion counseling to a pregnant adolescent if such adolescent and the parents or guardians of such adolescent request such referral; and grants may be made only to projects or programs which do not advocate, promote, or encourage abortion.

(b) The Secretary shall ascertain whether programs or projects comply with subsection (a) of this section and take appropriate action if programs or projects do not comply with such subsection, including withholding of funds.

(July 1, 1944, ch. 373, title XX, \$2011, as added Pub. L. 97–35, title IX, \$955(a), Aug. 13, 1981, 95 Stat. 592.)

SUBCHAPTER XIX—VACCINES

PRIOR PROVISIONS

A prior subchapter XIX (§300aa et seq.), comprised of title XXI of the Public Health Service Act, act July 1, 1944, ch. 373, §§2101 to 2116, was renumbered title XXIII, §§2301 to 2316, of the Public Health Service Act, and transferred to subchapter XXI (§300cc et seq.) of this chapter, renumbered title XXV, §§2501 to 2514, of the Public Health Service Act, and transferred to subchapter XXV (§300aaa et seq.) of this chapter, renumbered title XXVI, §§2601 to 2614, of the Public Health Service Act, renumbered title XXVII, §§2701 to 2714, of the Public Health Service Act, and renumbered title II, part B, §§231 to 244, of the Public Health Service Act, and transferred to part B (§238 et seq.) of subchapter I of this chapter.

PART 1—NATIONAL VACCINE PROGRAM

§ 300aa-1. Establishment

The Secretary shall establish in the Department of Health and Human Services a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The Program shall be administered by a Director selected by the Secretary.

(July 1, 1944, ch. 373, title XXI, §2101, as added Pub. L. 99–660, title III, §311(a), Nov. 14, 1986, 100 Stat. 3756.)

PRIOR PROVISIONS

A prior section 300aa-1, act July 1, 1944, §2102, was successively renumbered by subsequent acts and transferred, see section 238a of this title.

A prior section 2101 of act July 1, 1944, was successively renumbered by subsequent acts and transferred, see section 238 of this title.

EFFECTIVE DATE

Pub. L. 99-660, title III, §323, Nov. 14, 1986, 100 Stat. 3784, as amended by Pub. L. 100-203, title IV, §4302(a), Dec. 22, 1987, 101 Stat. 1330-221; Pub. L. 102-168, title II, §201(a), Nov. 26, 1991, 105 Stat. 1102, provided that: 'Subtitle 1 of title XXI of the Public Health Service Act [42 U.S.C. 300aa-1 et seq.] shall take effect on the date of the enactment of this Act [Nov. 14, 1986] and parts A and B of subtitle 2 of such title [42 U.S.C. 300aa-10 et seq., 300aa-21 et seq.] shall take effect on October 1, 1988 and parts C and D of such title [42 U.S.C. 300aa-25 et seq., 300aa-31 et seq.] and this title [probably means provisions of title III of Pub. L. 99-660 other than those that enacted this subchapter and redesignated former sections 300aa to 300aa-15 of this title as sections 300cc to 300cc-15 of this title; these other provisions amended sections 218, 242c, 262, 286, and 289f of this title and enacted provisions set out as notes under

sections 201, 300aa-1, and 300aa-4 of this title] shall take effect on the date of the enactment of the Vaccine Compensation Amendments of 1987 [Dec. 22, 1987]."

SEVERABILITY

Pub. L. 99–660, title III, $\S322$, Nov. 14, 1986, 100 Stat. 3783, as amended by Pub. L. 101–239, title VI, $\S6602$, Dec. 19, 1989, 103 Stat. 2293; Pub. L. 101–502, $\S5(g)(1)$, Nov. 3, 1990, 104 Stat. 1288, provided that:

"(a) IN GENERAL.—Except as provided in subsection (b), if any provision [of] part A or B of subtitle 2 of title XXI of the Public Health Service Act [42 U.S.C. 300aa–10 et seq., 300aa–21 et seq.], as added by section 311(a), or the application of such a provision to any person or circumstance is held invalid by reason of a violation of the Constitution, both such parts shall be considered invalid.

"(b) SPECIAL RULE.—If any amendment made by section 6601 of the Omnibus Budget Reconciliation Act of 1989 [Pub. L. 101–239, amending sections 300aa–10 to 300aa–17, 300aa–21, 300aa–23, 300aa–26, and 300aa–27 of this title] to title XXI of the Public Health Service Act [42 U.S.C. 300aa–1 et seq.] or the application of such a provision to any person or circumstance is held invalid by reason of the Constitution, subsection (a) shall not apply and such title XXI of the Public Health Service Act without such amendment shall continue in effect."

[Amendment by section 5(g)(1) of Pub. L. 101–502 to section 322(a) of Pub. L. 99–660, set out above, effective Nov. 14, 1986, see section 5(h) of Pub. L. 101–502, set out as an Effective Date of 1990 Amendment note under section 300aa–11 of this title.]

EVALUATION OF PROGRAM; STUDY AND REPORT TO CONGRESS

Pub. L. 101–239, title VI, §6601(t), Dec. 19, 1989, 103 Stat. 2293, as amended by Pub. L. 102–168, title II, §201(b), Nov. 26, 1991, 105 Stat. 1103, directed the Secretary of Health and Human Services to evaluate the National Vaccine Injury Compensation Program under this subchapter and report results of such study to Committee on Energy and Commerce of House of Representatives and Committee on Labor and Human Resources of Senate not later than Jan. 1, 1993.

RELATED STUDIES

Pub. L. 99-660, title III, §312, Nov. 14, 1986, 100 Stat. 3779, directed Secretary of Health and Human Services, not later than 3 years after the effective date of this title (see Effective Date note above), to conduct, through studies by the Institute of Medicine of the National Academy of Sciences or other appropriate nonprofit private groups or associations, a review of pertussis vaccines and related illnesses and conditions and MMR vaccines, vaccines containing material intended to prevent or confer immunity against measles, mumps, and rubella disease, and related illnesses and conditions, make specific findings and report these findings in the Federal Register not later than 3 years after the effective date of this title, and at the same time these findings are published in the Federal Register, propose regulations as a result of such findings, and not later than 42 months after the effective date of this title, promulgate such proposed regulations with such modifications as may be necessary after opportunity for public hearing.

STUDY OF OTHER VACCINE RISKS

Pub. L. 99–660, title III, $\S313$, Nov. 14, 1986, 100 Stat. 3781, provided that:

"(a) STUDY.—

"(1) Not later than 3 years after the effective date of this title [see Effective Date note above], the Secretary shall, after consultation with the Advisory Commission on Childhood Vaccines established under section 2119 of the Public Health Service Act [42 U.S.C. 300aa-19]—

"(A) arrange for a broad study of the risks (other than the risks considered under section 102 [21