

(2) Payment practices of third-party payment organizations, including other Federal programs such as titles XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in the particular area.

(c) A certification by a prescriber, pursuant to paragraph (a) of this section, that a brand of drug is medically necessary for a particular patient shall be in the prescriber's own handwriting, in such form and manner as the Secretary may prescribe. An example of an acceptable certification is the notation "brand necessary". A procedure for checking a box on a form will not constitute an acceptable certification.

PART 51a—PROJECT GRANTS FOR MATERNAL AND CHILD HEALTH

Sec.

51a.1 To whom does this regulation apply?

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AUTHORITY: Sec. 1102 of the Social Security Act, 49 Stat. 647 (42 U.S.C. 1302); sec. 502(a) of the Social Security Act, 95 Stat. 819-20 (42 U.S.C. 702(a)).

SOURCE: 51 FR 7727, Mar. 5, 1986, unless otherwise noted.

§ 51a.1 To whom does this regulation apply?

The regulation in this part applies to grants, contracts, and other arrangements under section 502(a) of the Social Security Act, as amended (42 U.S.C. 702(a)), for special projects of regional and national significance; maternal and child health or crippled children's research and training projects; genetic disease testing, counseling and information projects; and comprehensive hemophilia diagnostic and treatment centers.

§ 51a.2 Definitions.

Act means the Social Security Act, as amended.

Genetic diseases means inherited disorders caused by the transmission of certain aberrant genes from one generation to another.

Hemophilia means a genetically transmitted bleeding disorder resulting from a deficiency of a plasma clotting factor.

Institution of higher learning means any college or university accredited by a regionalized body or bodies approved for such purpose by the Secretary of Education, and any teaching hospital which has higher learning among its purposes and functions and which has a formal affiliation with an accredited school of medicine and a full-time academic medical staff holding faculty status in such school of medicine.

Secretary means the Secretary of Health and Human Services or his or her designee.

§ 51a.3 Who is eligible to apply for Federal funding?

Any public or private entity including an Indian tribe or tribal organization (as those terms are defined at 25 U.S.C. 450b) is eligible to apply for Federal funding for a special project of regional or national significance; genetic disease testing, counseling, and information project; comprehensive hemophilia diagnostic and treatment center; or for a special maternal and child health improvement project. Only public or nonprofit private institutions of higher learning may apply for training grants. Only public or nonprofit institutions of higher learning and public or private nonprofit agencies engaged in research or programs relating to maternal and child health and crippled children's services programs may apply for grants, contracts or jointly financed cooperative agreements for research in maternal and child health services or crippled children's services.

§ 51a.4 How is application made for Federal funding?

The application must include a budget and narrative plan of the manner in which the project has met,

or plans to meet, each of the requirements prescribed by the Secretary. The plan must describe the project in sufficient detail to identify clearly the nature, need, and specific objectives of, and methodology for carrying out, the project. Since the Department anticipates a limited number of renewals, the application must include (except for research projects described at the end of this paragraph) a description of the project's past attempts and current plans to secure other sources of funding.

By their very nature, research projects are generally not continuing activities and do not generate reimbursement. They are therefore not included under the requirement in this paragraph to provide information on other sources of funding.

(Approved by the Office of Management and Budget under control number 0915-0050)

§ 51a.5 What criteria will DHHS use to decide which projects to fund?

(a) The Secretary will determine the allocation of funds available under section 502(a) of the Act for each of the activities described in § 51a.1.

(b) Within the limit of funds determined by the Secretary to be available for each of the activities described in § 51a.1, the Secretary may award Federal funding for projects under this part to applicants which will, in his or her judgment, best promote the purpose of title V of the Social Security Act taking the following factors equally into account:

- (1) The quality of the project plan or methodology.
- (2) The need for the services, research, or training.
- (3) The cost-effectiveness of the proposed project relative to the number of persons proposed to be benefitted, served or trained, taking into consideration, where relevant, whether the proposed project is urban or rural and the special circumstances associated with providing care or training in various areas.
- (4) The extent to which the project will contribute to the advancement of maternal and child health and crippled children's services.

(5) The extent to which rapid and effective use of grant funds will be made by the project.

(6) The effectiveness of procedures to collect the cost of care and services from third-party payment sources (including government agencies) which are authorized or under legal obligation to make such payments for any service (including diagnostic, preventive and treatment services).

(7) The extent to which the project will be integrated with the administration of the Maternal and Child Health Services block grants and other block grants made to the appropriate State(s).

(8) The soundness of the project's management, considering the qualifications of the staff of the proposed project and the applicant's facilities and resources.

§ 51a.6 What confidentiality requirements must be met?

All information as to personal facts and circumstances obtained by the project's staff about recipients of services shall be held confidential, and shall not be disclosed without the individual's consent except as may be otherwise required by applicable law or as may be necessary to provide for medical audits by the Secretary with appropriate safeguards for confidentiality of patient records. Otherwise, information may be disclosed only in summary, statistical, or other form which does not identify particular individuals.

§ 51a.7 What other DHHS regulations apply?

(a) Several other DHHS regulations apply to awards under this part. These include, but are not limited to:

42 CFR Part 50—Policies of general applicability:

Subpart B—Sterilization of persons in federally assisted family planning projects.

Subpart C—Abortions and related medical services in federally assisted programs of the Public Health Service.

Subpart E—Maximum allowable cost for drugs.

42 CFR Part 122 Health systems agencies:

Subpart E—Health systems agency reviews of certain proposed uses of Federal health funds.

45 CFR Part 19—Limitations on payment or reimbursement for drugs

45 CFR Part 80—Nondiscrimination under programs receiving Federal assistance through the Department of Health and Human Services—Effectuation of Title VI of the Civil Rights Act of 1964

45 CFR Part 81—Practice and procedure for hearings under part 80 of this title

45 CFR Part 84—Nondiscrimination on the basis of handicap in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 86—Nondiscrimination on the basis of sex in programs and activities receiving or benefiting from Federal financial assistance

45 CFR Part 91—Nondiscrimination on the basis of age in HHS programs or activities receiving Federal financial assistance.

(b) In addition to the above regulations, the following apply to projects funded through grants:

45 CFR Part 50 Policies of general applicability

Subpart D—Public Health Service grant appeals procedure.

45 CFR Part 16—Procedures of the Departmental Grant Appeals Board

45 CFR Part 74—Administration of grants

45 CFR Part 75—Unformal grant appeals procedures

PART 51b—PROJECT GRANTS FOR PREVENTIVE HEALTH SERVICES

Subpart A—General Provisions

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Subpart E—[Reserved]

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51b.601 To which programs does this subpart apply?

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51b.603 What are the confidentiality requirements?

51b.604 What information is required in the application?

51b.605 How will grant applications be evaluated and the grants awarded?

51b.606 How can grant funds be used?

AUTHORITY: Secs. 317 and 318, Public Health Service Act, 92 Stat. 3574 and 3582 (42 U.S.C. 247b, 247c); sec. 1743 Pub. L. 97-35, 95 Stat. 763 (31 U.S.C. 1243 note).

Subpart A—General Provisions

SOURCE: 48 FR 4473, Feb. 1, 1983, unless otherwise noted.

§ 51b.101 To which programs do these regulations apply?

The regulations in this part apply to grants for preventive health service programs authorized under section 317 (42 U.S.C. 247b) and for venereal disease prevention and control programs authorized under section 318 (42 U.S.C. 247c) of the Act.

§ 51b.102 Definitions.

As used in these regulations: