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## **DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Public Health Service**

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**PROPOSED REGULATION  
OF PROJECT GRANTS  
FOR SUDDEN INFANT  
DEATH SYNDROME  
INFORMATION AND  
COUNSELING**

**DEPARTMENT OF HEALTH,  
EDUCATION, AND WELFARE**

Public Health Service

[ 42 CFR Part 51a ]

**PROJECT GRANTS FOR SUDDEN INFANT  
DEATH SYNDROME INFORMATION AND  
COUNSELING**

**Notice of Proposed Rulemaking**

Notice is hereby given that the Assistant Secretary for Health, with approval of the Secretary of Health, Education, and Welfare proposes to add a new Subpart E, entitled, "Project Grants for Sudden Infant Death Syndrome Information and Counseling," to Part 51a of Title 42, Code of Federal Regulations. The purpose of the new Subpart E of Part 51a is to establish regulations governing grants to public and nonprofit private entities under section 1121(b) of the Public Health Service Act (42 U.S.C. 300c-11) for projects which include both the collection, analysis and furnishing of information relating to the causes of, and the provision of information and counseling to families affected by, the sudden infant death syndrome.

Section 1121(b) also provides that the Secretary may carry out the provisions of subsection (b) by means of contracts with public and private entities. However, the Secretary is currently exploring the issues raised by assistance-type contracts, a mechanism which has heretofore not been used in public health assistance programs. Accordingly, it was considered advisable in the interest of starting the program mandated by section 1121(b) at the earliest date possible to publish initially only the regulations covering grants under section 1121(b). Regulations governing contracts under section 1121(b) will be published at a later date.

Interested persons are invited to submit written comments, suggestions, or objections concerning the proposed regulations to the Director, Division of Policy Development, Bureau of Community Health Services, Health Services Administration, Room 6-17, 5600 Fishers Lane, Rockville, Md. 20852, on or before April 4, 1975. All comments received in timely response to this notice will be considered and will be available for public inspection in the above named office during regular business hours.

It is therefore proposed to amend Part 51a of Title 42 by changing the title thereof to "Grants for Maternal and Child Health" and by adding thereto a new Subpart E, as set forth below.

Dated: January 17, 1975.

CHARLES C. EDWARDS,  
Assistant Secretary for Health.

Approved: February 24, 1975.

CASPAR W. WEINBERGER,  
Secretary.

Subpart E—Project Grants for Sudden Infant  
Death Syndrome Information and Counseling

**PART 51a—GRANTS FOR MATERNAL AND  
CHILD HEALTH AND CRIPPLED CHILDREN'S SERVICES**

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AUTHORITY: Sec. 215, 58 Stat. 690, as amended (42 U.S.C. 216); Sec. 1121, 88 Stat. 91 (42 U.S.C. 300c-11).

**Subpart E—Project Grants for Sudden Infant  
Death Syndrome Information and  
Counseling**

**§ 51a.501 Applicability.**

The regulations of this subpart are applicable to grants to public and nonprofit private entities pursuant to section 1121(b) of the Public Health Service Act (42 U.S.C. 300c-11) for projects for the collection, analysis and furnishing of information relating to the causes of the sudden infant death syndrome and the provision of information and counseling to families affected by the sudden infant death syndrome.

**§ 51a.502 Definitions.**

As used in this subpart:

- (a) "Act" means the Public Health Service Act, as amended.  
(b) "Secretary" means the Secretary of Health, Education, and Welfare and any other officer or employee of the Department of Health, Education, and Welfare to whom the authority involved has been delegated.  
(c) "Nonprofit" as applied to a private entity means that no part of the net earnings of such entity inures, or may lawfully inure, to the benefit of any private shareholder or individual.  
(d) "The Sudden Infant Death Syndrome," for the purpose of this regulation, means the sudden death of any infant which is unexpected by history, and in which a thorough post mortem examination fails to demonstrate an adequate cause for death.  
(e) "SIDS" means the sudden infant death syndrome.  
(f) "Family" means the relatives of a SIDS victim or any persons functioning in loco parentis to such victim at the time of a SIDS death.  
(g) "Applicant" means a public or nonprofit private entity which applies for a grant.

**§ 51a.503 Eligibility.**

- (a) *Eligible applicants.* Any public or nonprofit private entity is eligible to apply for a grant under this subpart.  
(b) *Eligible projects.* Grants to eligible applicants may be made by the Secretary for projects which include both:  
(1) The collection, analysis, and furnishing of information (derived from post mortem examinations and other means) pertaining to the causes of SIDS; and  
(2) The provision of information and counseling to families affected by SIDS.

**§ 51a.504 Application for a grant.**

(a) An application for a grant under this subpart shall be submitted to the Secretary at such time and in such form and manner as the Secretary may prescribe. The application shall contain:

- (1) A full and adequate description of the project and of the manner in which the applicant intends to conduct the project and carry out the requirements of this subpart;  
(2) A budget and justification of the amount of grant funds requested;  
(3) Such other pertinent information as the Secretary may require.  
(b) The application must be executed by an individual authorized to act for the applicant and to assume for the applicant the obligations imposed by the regulations of this subpart and any additional conditions of the grant.

(c) The application shall:

- (1) Provide that the project will be administered by or under the supervision of the applicant;  
(2) Provide, in accordance with the provisions of § 51a.506, that the project will have appropriate community representation in its development and operation;  
(3) Set forth such fiscal controls and fund accounting procedures, in accordance with the provisions of § 51a.516, as may be necessary to assure proper disbursement of and accounting for grant funds paid to the applicant; and  
(4) Provide for making such reports, in addition to the performance report required by § 51a.514, in such form and containing such information as the Secretary may from time to time reasonably require.

**§ 51a.505 Project requirements.**

An approvable application must contain each of the following:

- (a) A description, together with supporting materials, of how the project will:  
(1) Establish a mechanism, or utilize a mechanism already existing in the community by which to identify possible SIDS deaths.  
(2) Encourage and, where necessary, arrange for or provide appropriate medical investigations of the cause of death performed in accordance with appropriate medical standards when possible SIDS deaths are identified.  
(3) Obtain and provide pertinent information from medical investigations of probable SIDS deaths by board qualified or board eligible medical pathologists or other persons authorized by law to perform such investigations.  
(4) Identify and, where possible, utilize third-party sources of payment for appropriate medical investigations of probable SIDS deaths.  
(5) Encourage the use of SIDS as a diagnosis on death certificates, or as the cause of death on death certificates, when medically determined.  
(6) Provide information concerning SIDS to families affected by SIDS, including providing or arranging for prompt diagnosis of the cause of death and notification of the family of the

diagnosis within 24 hours of the diagnosis where possible.

(7) Provide for voluntary counseling of families affected by SIDS, including home visits and other followup in accordance with the families' needs, by personnel qualified by training and experience to provide such services. Such personnel must be fully knowledgeable about the management of SIDS and of problems associated with death, grief, and mourning. Such counseling services shall be provided by:

(1) project personnel; and

(ii) as necessary or appropriate to meet the families' needs, other counseling resources within the community.

(8) Maintain consultation and arrangements with other community resources, such as clergy, police, emergency personnel, mental health services, organized parents' groups, and other voluntary organizations, for

(1) Referral of families affected by SIDS, as appropriate, to such resources; and

(ii) Furnishing directly or indirectly information and suggestions for dealing with SIDS cases to such community resources.

(9) Collect information on SIDS cases in the project area including demographic data, epidemiological data, and therapeutic management data.

(10) Provide information gathered under subparagraph (9) above, in accordance with § 51a.511, to:

(1) Appropriate public officials; and

(ii) Interested members of the general public in the project area.

(b) Assurances that:

(1) Services will be made available without the imposition of any durational residence or referral requirement;

(2) Services will be made available without regard to religion, creed, age, sex, parity, marital status, or income; and

(3) Services will be made available in such a manner as to protect the dignity of the individual.

#### § 51a.506 Project community council.

(a) A project community council shall be established by the grantee and shall consist of a minimum of nine and a maximum of fifteen members. At least one-third of such members shall be representatives of the community being served by the project, including representatives of parents' groups or other voluntary civic or community organizations. The membership shall also include representatives of health care or public safety professions, such as medical examiners, public health nurses, private physicians, police and fire department representatives, and funeral directors.

(b) The process of selection of its members shall be stipulated in the council's bylaws, which shall be subject to approval by the Secretary and must provide that:

(1) Members shall serve for definite terms which shall not exceed four years, so staggered as to assure that the terms of not more than one-third of the members shall expire in any calendar year.

(2) The council shall meet as often as necessary, but not less than six times per year, for the purpose of considering and, as appropriate, consulting with an advising grantee with respect to:

(i) The project's progress toward achieving its goals of service to the area, and

(ii) Review and modification of the project's existing functions, as necessary.

(iii) All recommendations of the council with respect to the project's activities shall be available to the public.

(iv) Written minutes shall be kept of all council meetings.

(c) The Secretary may, for good cause shown, allow a grantee a period of time, not to exceed three months from the date of the receipt of a grant awarded under section 1121(b) of the Act, for compliance with the requirements of this section. In addition, in the case of a grantee which is a State or local governmental agency and which has demonstrated to the satisfaction of the Secretary that it is unable, under State or local law, to establish a project community council pursuant to paragraph (a) of this section, the Secretary may allow such grantee a reasonable period of time to take the appropriate steps to have such legal disability removed. *Provided*, That, such grantee, in the interim, must establish alternate procedures, approved by the Secretary, to assure maximum community participation in the development and operation of the project.

#### § 51a.507 Evaluation and grant award.

(a) Within the limit of funds available for such purposes, the Secretary may award grants to assist in the establishment and operation of those projects which will, in his judgment, best promote the purposes of section 1121(b) of the Act, taking into account:

(1) The need for the project's services and informational materials to be provided, including the relative extent to which the project will contribute to the development of a nationwide distribution of such services and materials;

(2) The applicant's demonstration of an understanding of the problem, including the incidence of SIDS and the handling of the problem in the project area;

(3) The capability of the applicant to provide services and informational materials of high quality and effectiveness; and

(4) The degree to which the project plan adequately provides for the elements set forth in § 51a.505.

(b) In determining priority in awarding grants under section 1121(b) of the Act, the Secretary will take into consideration the relative extent to which the project:

(1) Would serve an area with a population of one million or more persons;

(2) Would be located in an area with an infant mortality rate higher than the national average;

(3) Has community resources available which will enable it to meet the requirements of § 51a.505 and;

(4) Is assured of community support and provides an indication of how con-

tinuation of its services will be maintained after Federal funding is concluded.

(c) The amount of any award will be determined by the Secretary on the basis of his estimate of the sum necessary for the proper performance of the project. In determining the grantee's share of project costs, if any, costs borne by Federal funds, or costs used to match other Federal grants may not be included except as may be otherwise provided by law.

(d) All grant awards shall be in writing, shall set forth the amount of funds granted, and the period for which support is recommended.

(e) Neither the approval of any project nor any grant award shall commit or obligate the United States in any way to make additional, supplemental, continuation, or other award with respect to any approved project or portion thereof. For continuation support, grantees must make separate application periodically at such times and in such form as the Secretary may direct.

#### § 51a.508 Payments.

The Secretary shall from time to time make payments to a grantee of all or portion of any grant award either in advance or by way of reimbursement for expenses incurred in the performance of the project, to the extent he determines such payments necessary to promote prompt initiation and advancement of the approved project.

#### § 51a.509 Use of project funds.

Any funds granted pursuant to this subpart as well as other funds to be used in performance of the approved project may be expended solely for carrying out the approved project in accordance with the applicable statute, the regulations of this subpart, the terms and conditions of the award, and the applicable cost principles prescribed by Subpart Q of 45 CFR, Part 74. Project grant funds may be used for appropriate medical investigations of probable SIDS deaths, such as autopsies performed in accordance with appropriate medical standards, by a board certified or board eligible medical pathologist or other person qualified by law to perform such medical investigations, but only where the following conditions are met:

(a) No other source of funds for such investigations is available;

(b) The cost of such investigations is reasonable;

(c) The results of such investigations are used only for the collection, analysis and furnishing of information relating to the causes of SIDS; and

(d) The results of such investigations are made available to the families of suspected SIDS victims unless medically contraindicated.

#### § 51a.510 Civil rights.

Attention is called to the requirements of title VI of the Civil Rights Act of 1964 (78 Stat. 252 (42 U.S.C. 2000d et seq.)), and in particular section 601 of such Act which provides that no person in the United States shall on the grounds of

race, color, or national origin be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance. A regulation implementing such title VI, which applies to grants made under this part, has been issued by the Secretary with the approval of the President (45 CFR Part 80). In addition, no person shall be denied employment in or by such program or activity on the grounds of age, sex, creed, or marital status.

**§ 51a.511 Confidentiality of information.**

All information as to personal facts and circumstances obtained by the project staff in connection with the provision of services under the project shall be treated as privileged communications, shall be held confidential, and shall not be divulged without the individual's consent except as may be necessary to provide services to the individual. Such information may be disclosed in summary, statistical, or other form which does not identify particular individuals.

**§ 51a.512 Publications and copyright.**

Except as may otherwise be provided under the terms and conditions of the award, the grantee may copyright without prior approval any publication, films or similar materials developed or resulting from a project supported by a grant under this part, subject, however, to a royalty-free, nonexclusive, and irrevocable license or right in the Government to reproduce, translate, publish, use, disseminate, and dispose of such materials and to authorize others to do so. Royalties received by grantees from copyrights on publications or other works developed under the grant shall first be used to reduce the Federal share of the grant to cover the costs of publishing or producing the materials and any royalties in excess of the costs of publishing or producing such materials shall be distributed in accordance with Chapter 1-420 of the

Department of Health, Education, and Welfare Grants Administration Manual.<sup>1</sup>

**§ 51a.513 Grantee accountability.**

(a) *Accounting for grant award payments.* All payments made by the Secretary shall be recorded by the grantee in accounting records separate from the records of all other grant funds, including funds derived from other grant awards. With respect to each approved project the grantee shall account for the sum total of all amounts paid by presenting or otherwise making available evidence satisfactory to the Secretary of expenditures for direct and indirect costs meeting the requirements of this subpart. *Provided, however,* That when the amount awarded for indirect costs was based on a predetermined fixed percentage of estimated direct costs, the amount allowed for indirect costs shall be computed on the basis of such predetermined fixed-percentage rates applied to the total, or a selected element thereof, of the reimbursement direct costs incurred.

(b) *Grant closeout.* (1) Date of final accounting. A grantee shall render, with respect to each approved project, a full account, as provided herein, as of the date of the termination of grant support. The Secretary may require other special and periodic accounting.

(2) Final settlement. There shall be payable to the Federal government as final settlement with respect to each approved project the total sum of:

(i) Any amount not accounted for pursuant to paragraph (a) of this section.

(ii) Any credits for earned interest pursuant to paragraph (b) of this section.

(iii) Any other amounts due pursuant to Subparts F, M, and O of 45 CFR Part 74. Such total sum shall constitute a debt owed by the grantee to the Federal government and shall be recovered from

<sup>1</sup>The Department of Health, Education, and Welfare Grants Administration Manual is available for public inspection and copying at the Department and Regional Offices' information centers listed in 45 CFR Part 531 and may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

the grantee or its successors or assignees by setoff of other action as provided by law.

**§ 51a.514 Performance report.**

With each continuation or renewal application or with each financial status report at the end of a project period, whichever is appropriate, grantees shall submit a performance report for each grant which briefly presents the following for each program, functions, or activity involved:

(a) A comparison of actual accomplishments to the goals established for the period. Where the output of grant programs can be quantified, such quantitative data should be related to cost data for computation of unit costs.

(b) An explanation when established goals have not been met.

(c) Other pertinent information including, when appropriate, analysis and explanation of cost overruns or higher than anticipated unit costs.

**§ 51a.515 Additional conditions.**

The Secretary may with respect to any grant award impose additional conditions prior to or at the time of any award when in his judgment such conditions are necessary to assure or protect advancement of the approved project, the interests of public health, or the conservation of grant funds.

**§ 51a.516 Applicability of 45 CFR Part 74.**

The relevant provisions of the following subparts of 45 CFR Part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart:

45 CFR PART 74

SUBPART

- A—General
- B—Cash Depositories
- C—Bonding and Insurance
- D—Retention and Custodial Requirements for Records
- F—Grant—Related Income
- K—Grant Payment Requirements
- L—Budget Revision Procedures
- M—Grant Closeout, Suspension, and Termination
- O—Property
- Q—Cost Principles

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