Only PCBs in concentrations below 500 ppm can be destroyed in a high-efficiency boiler approved under § 761.60(a)(3).

(3) An incinerator approved under section 3005(c) of the Resource Conservation and Recovery Act (42 U.S.C. 6925(c)) (RCRA). Only PCBs in concentrations below 50 ppm can be destroyed in a RCRA-approved incinerator. The manufacturer seeking to qualify a process as a controlled waste process by disposing of wastes in a RCRA-approved incinerator must make a determination that the incinerator is capable of destroying less readily burned compounds than the PCB homologs to be destroyed. The manufacturer may use the same guidance used by EPA in making such a determination when issuing an approval under section 3005(c) of RCRA. The manufacturer is also responsible for obtaining a reasonable assurance that the incinerator, when burning PCB wastes, will be operated under conditions which have been shown to enable the incinerator to destroy the less readily burned compounds.

[FR Doc. 83-2700 Filed 1-31-83; 8:45 am]
BILLING CODE 6560-50-M

GENERAL SERVICES ADMINISTRATION

41 CFR Part 5-3

[APD 2800.2 CHGE 29]

Procurement by Negotiation; Structured Approach Profit/Fee Objective

AGENCY: General Services Administration.

ACTION: Final rule.

SUMMARY: The General Services Administration Procurement Regulations GSPR, Chapter 5, are amended to prescribe uniform policies for establishing profit or fee prenegotiation objectives in acquisitions requiring cost analysis. The basis for the regulation is Office of Federal Procurement Policy (OFPP) Policy Letter 80-7, dated December 9, 1980, (45 FR Part 82593, December 15, 1980), and the implementation of the Policy Letter in the Federal Procurement Regulations on October 14, 1982, (47 FR 50251, November 5, 1982). The GSPR satisfies the OFPP policy letter requirement that each agency meeting threshold requirements develop an individual structured approach for determining profit or fee objectives. The intended effect is to provide a structured approach for determining profit or fee objectives.

EFFECTIVE DATE: February 14, 1983.

FOR FURTHER INFORMATION CONTACT: Mr. Philip G. Read, Director, Office of Federal Procurement Regulations, Office of Acquisition Policy, (202-523-4755).

List of Subjects in 41 CFR Part 5-3

Accounting, Cost accounting standards, Government procurement, and Procurement by negotiation.

PART 5-3—PROCUREMENT BY NEGOTIATION

1. The table of contents for Subpart 5-3.8, is revised by adding the following:

Sec.

* * * * *

Authority: (Sec. 205(c), 63 Stat. 390; (40 U.S.C 486(c)).

2. Section 5-3.808-3, Structured approach for determining profit/fee objectives, is added to read as follows:

§ 5-3.808-3 Structured approach for determining profit fee objectives.

(a) General

(1) The structured approach provides contracting officers with a technique that will ensure consideration of the relative value of prescribed profit factors for the conduct of negotiations. The contracting officer's analysis of these profit factors is based on information available to the Government before negotiations. Such information is furnished in proposals, audit data, performance reports, preaward surveys and the like. The structured approach also provides a basis for documentation of a profit objective, including an explanation of any significant departure from this objective in reaching a final agreement. The extent of documentation should be directly related to the dollar value and complexity of the proposed procurement.

(2) The negotiation process does not require agreement on estimated cost elements or profit elements. The profit objective is a part of an overall negotiation objective. Specific agreement on the exact weights or values of the individual factors is not required and should not be attempted.

(3) When cost analysis is performed pursuant to § 1-3.807-2(c) of this title, profit consideration shall be in accordance with the structured approach set forth in paragraph (c) of this section. The structured approach shall be used in all contracts, including lease alterations, where cost analysis is performed except as set forth in paragraph (b) of this section.

(b) Exemptions from requirement to use the structured approach.

(1) Under exempted procurements, other methods for establishing profit objectives may be used. Generally, such methods will be supported in a manner similar to that used in the structured approach (profit factor breakdown and documentation of profit objective). However, factors within the structured approach considered inapplicable to the procurement shall be excluded from the profit objectives. The following type of procurements are exempt from the structured approach:

(i) Management contracts for operation and/or maintenance of Government facilities;

(ii) Contracts primarily requiring delivery of material supplied by subcontractors;

(iii) Termination settlements;

(iv) Cost-plus-award-fee contracts;

(v) Contracts where only price analysis is required (FPR 1-3.807-2(a));

(vi) Contracts and contract modifications of $100,000 or less in value; and

(vii) Architect-engineer and construction contracts.

(2) Other exemptions may be made in the negotiation of contracts having unusual pricing situations where the structured approach is determined to be unsuitable. Such exemptions shall be justified in writing and approved by the head of the procuring activity.

(c) Profit factors and weight ranges for use in the structured approach.

(1) The following factors shall be considered in all situations in which profit is to be specifically negotiated. The weight ranges listed after each factor shall be used when the structured approach is used.

Profit factors	Weight ranges (percent)
Contractor effort:	
Material acquisition	1 to 4
Direct labor	4 to 12
Overhead	3 to 8
Other costs	1 to 3
General management	4 to 8
Other factors:	
Cost risk	0 to 7
Investment	−2 to +2
Performance	−2 to +2
Socio-economic programs	−.5 to +.5
Special situations	−2 to +2

(2) GSA Form 1766, Structured Approach Profit/Fee Objective, shall be used to facilitate the profit objective computation. The contracting officer shall measure the "Contractor Effort" by the assignment of a profit percentage

within the designated weight ranges to each element of cost recognized. The amount calculated for facilities capital cost of money shall not be included in the cost base for the computation of the profit objective (see §§ 1-15.205-51(a) and 1-3.1301).

(3) The categories listed under "Contractor Effort" are for reference purposes only. Often individual proposals will be in a different format; but since these categories are broad and basic they provide sufficient guidance to evaluate all items of cost.

(4) After computing a total dollar profit for "Contractor Effort", the contracting officer shall calculate the specific profit dollars for cost risk, investment, performance, socio-economic programs, and special situations. This is accomplished by multplying the total Government cost objective, exclusive of any cost of money for facilities capital, by the specific weights assigned to the elements within the "Other Factors" category.

(5) In determining the value of each factor, the contracting officer should be governed by the definition, description, and purpose of the factors together with considerations for evaluating them as set forth in paragraphs (d) and (e) of this section.

(d) Considerations for assigning weights to the "Contractor Effort" category.

The "Contractor Effort" category measures how much the contractor is expected to contribute to the overall effort necessary to meet the contract performance requirements in an efficient manner. This factor, which is apart from the contractor's responsibility for contract performance, takes into account what resources are necessary and what the contractor must do to accomplish conversion of ideas and materials into the final product called for in the contract. This is a recognition that within a given performance output, or within a given sales dollar figure, necessary efforts on the part of individual contractors can vary widely in both value and quantity, and that the profit objective should reflect the extent and nature of the contractor's contribution to total performance. A major consideration is the difficulty or complexity of the work to be performed, and the unusual demands of the contract, such as whether the project involves a new approach unrelated to past experience or only refinements on existing technology. The evaluation of this factor requires an anlysis of the cost content of the proposed contract as follows:

(1) *Material acquisition (subcontracted items, purchased parts, special tooling, and other material).*

(i) Analysis of these cost items for the purpose of assigning profit weights shall include an evaluation of the managerial and technical effort necessary to obtain the required purchased parts, subcontracted items, and other materials, including special tooling. This evaluation shall include consideration of the number of orders and suppliers, and whether established sources are available or new sources must be developed. The contracting officer shall also determine whether the contractor will, for example, obtain the material and tooling by routine orders from readily available supplies (particularly those of substantial value in relation to the total contract cost), or by detailed subcontracts for which the prime contractor will be required to develop complex specifications involving creative design or close tolerance manufacturing requirements. Consideration should be given to the managerial and technical efforts necessary for the prime contractor to administer subcontracts, and select subcontractors, including efforts to break out subcontracts from sole sources, through the introduction of competition. These determinations should also be made for purchases of raw materials or basic commodities.

(ii) Recognized costs proposed as direct material costs, such as scrap charges, shall be treated as material for profit evaluation. If intracompany transfers are accepted at price in accordance with § 1-15.205-22(e), they shall be evaluated by individual components of cost, i.e., material, labor, and overhead.

(2) *Direct labor (engineering, professional services, manufacturing, and other labor).* Analysis of the various labor items of the cost content of the contract for the purpose of assigning profit weights should include evaluation of the comparative quality and level of the engineering or professional talents, service contract labor, manufacturing, skills, and experience to be employed. In evaluating professional or engineering labor, consideration should be given to the amount of notable, unusual, or scarce talent needed in contrast to journeyman effort or supporting personnel. The diversity, or lack thereof, of professional or engineering specialities required for contract performance and the corresponding need for supervision and coordination should be evaluated. Such circumstances as whether the caliber or class of an engineer involved is that of an "idea-man," or whether the contractor is required by the nature of the contract to assign unusually skilled talent to the work, should be considered as part of the evaluation. Service contract labor should be evaluated in a like manner by assigning higher weights to engineering or professional type skills and lower weights to semi-professional or other type skills required for contract performance. Similarly, the variety of manufacturing and other categories of labor skills required and the contractor's manpower resources for meeting these requirements should be considered. For purposes of evaluation, categories of labor (i.e., construction, quality control, receiving, inspection etc.) which do not fall within professional, engineering, service or manufacturing labor may be categorized as appropriate. However, the same evaluation considerations as outlined above shall be applied.

(3) *Overhead and general management.*

(i) Analysis of conversion related indirect costs (overhead) and general management costs (general and administrative expense (G&A)) includes an evaluation of the make-up of these expenses and how much they contribute to contract performance. To the extent practicable, analysis for the purpose of assigning profit weights should include a determination of the amount of labor within these overhead pools and how this labor would be treated if it were considered as direct labor under the contract. The allocable labor elements should be given the same profit consideration that they would receive if they were treated as direct labor. The other elements of these overhead pools should be evaluated to determine whether they are routine expenses such as utilities and maintenance, and hence given lesser profit consideration, or whether they are significant contribution elements. The composite of the individual determinations in relation to the elements of the overhead pools will be the profit consideration given the pools as a whole.

(ii) It is not necessary that the contractor's accounting system break down overhead expenses within the classification of engineering overhead, manufacturing overhead, other overhead pools, and general and administrative expenses, unless dictated otherwise by applicable Cost Accounting Standards (CAS). The contractor whose accounting system only reflects one overhead rate on all direct labor need not change its system (if CAS exempt) to correspond with the above classifications. The contracting officer, in an evaluation of such a contractor's overhead rate, could break out the applicable sections of the composite rate which would be classified as engineering overhead, manufacturing overhead, other overhead pools and general and administrative expenses, and follow the appropriate evaluation technique.

(iii) Management problems surface in various degrees and the management expertise exercised to solve them should be considered as an element of profit. For example, a new program for an item which involves advanced state of the art techniques will cause more problems and require more managerial time and abilities of a higher order, than one which is a follow-on contract. If new contracts create more problems and require a higher profit weight, follow-ons should be adjusted downward as many of the problems should have been solved. In any event, an evaluation should be made of the underlying managerial effort involved on a case-by-case basis.

(iv) It may not be necessary for the contracting officer to make a separate profit evaluation of overhead expenses in connection with each procurement action for substantially the same product with the same contractor. Where an analysis of the profit weight to be assigned to the overhead pool has been made, that weight assigned may be used for future procurements with the same contractor until there is a change in the cost composition of the overhead pool or the contract circumstances, or the factors discussed in paragraph (d)(3)(iii) of this section are involved.

(4) *Other costs.* Include all other direct costs associated with contractor performance under this item (e.g., travel and relocation, direct support, and consultants). Analysis of these items of costs for the purpose of assigning profit weights shall include: (i) The significance of the costs, (ii) the nature of the costs, and (iii) how much they contribute to contract performance.

(e) Considerations for assigning weights to the "Other Factors" category.

(1) *Contract cost risk.* The degree of risk assumed by the contractor should influence the amount of profit or fee a contractor is entitled to anticipate. For example, where a portion of the contract cost risk has been shifted to the Government throught cost-reimbursement or price-redetermination provisions, unusual contingency provisions, or other risk-reducing measures, the amount of profit or fee should be less than where the contractor assumes all the risk. The contracting officer will need to consider the type of contract anticipated and the contractor risk associated therewith when selecting the position in the weight range for profit that is appropriate for the risk to be borne by the contractor. This factor is one of the most important in arriving at prenegotiation profit objectives.

(i) Evaluation of contract cost risk requires a determination of (A) The degree of cost responsibility the contractor assumes, (B) the reliability of the cost estimates in relation to the task assumed, and (C) the complexity of the task assumed by the contractor. This factor is specifically limited to the risk of contract cost. Thus, such risks on the part of the contractor as reputation, losing a commercial market, or risk of losing potential profits in other fields are not within the scope of this factor.

(ii) The first and basic determination of the degree of cost responsibility assumed by the contractor is related to the sharing of the total risk of contract cost by the Government and the contractor through the selection of contract type. The extremes are a cost-plus-a-fixed-fee contract requiring the contractor to use his best efforts to perform a task, and a firm fixed-price contract for a complex item. A cost-plus-a-fixed-fee contract would reflect a minimum assumption of cost responsibility, whereas a firm fixed-price contract would reflect a complete assumption of cost responsibility. Where proper contract type selection has been made, the reward for risk by contract type would usually fall into the following percentage ranges:

	Percent
Cost reimbursement type contracts	0 to 3.
Fixed-price type contracts	3 to7.

(A) Within the above ranges, a cost-plus-a-fixed-fee contract normally would not justify a reward for risk in excess of 0%, unless the contract contains cost risk features such as ceilings on overheads. In such cases, up to 1% may be justified. Cost-plus-incentive-fee contracts fill the remaining portion of the 0 to 3 percent range with weightings directly related to such factors as confidence in target cost, share ratio of fee(s), etc. The weight range for fixed-price contracts is wide enough to accommodate the many types of fixed-price arrangements. These include fixed-price incentive, firm fixed-price with economic price adjustment, fixed-price with prospective or retroactive price determination, and firm fixed-price contracts. Weighting should be indicative of the cost risk assumed, with only firm fixed-price contracts reaching the top end of the range.

(B) The contractor's subcontracting program may have significant impact on the contractor's acceptance of risk under a contract form. It could cause risk to increase or decrease in terms of both cost and performance. This consideration should be a part of the contracting officer's overall evaluation in selecting a factor to apply for cost risk. It may be determined, for instance that the prime contractor has effectively transferred real cost risk to a subcontractor and the contract cost risk evaluation may, as a result, be below the range which would otherwise apply for the contract type being proposed. The contract cost risk evaluation should not be lowered, however, merely on the basis that a substantial portion of the contract cost represents subcontracts without any substantial transfer of contractor's risk.

(C) In making a contract cost risk evaluation in procurement actions that involve definitization of letter contracts, unpriced change orders, and unpriced orders under basic ordering agreements; consideration should be given to the effect on total contract cost risk as a result of having partial performance before definitization. Under some circumstances it may be reasoned that the total amount of cost risk has been effectively reduced. Under other circumstances, it may be apparent that the contractor's cost risk remained substantially unchanged. To be equitable, the determination of a profit weight for application to the total of all recognized costs, both those incurred and those yet to be expended, must be made with consideration to all attendant circumstances; not just to the portion of costs incurred or percentage of work completed prior to definitization.

(D) Time and materials contracts, labor-hour contracts, and overhaul contracts priced on a time and material basis shall be considered to be cost-plus-a-fixed-fee contracts for the purpose of establishing profit weights.

(E) Service contracts, such as janitorial, guard service, etc., shall have a weight range for cost risk of 0 to 4%. There may be instances where a firm fixed-price contract, which is not priced on a labor-hour method, warrants additional consideration for contractor cost risk. In those circumstances, a weight of up to 4% is authorized. Conversely, a cost-plus-a-fixed-fee service contract normally should be priced using a zero cost risk factor.

(iii) The second determination of the degree of cost responsibility assumed relates to the reliability of the cost estimate. Sound price negotiation requires well defined contract objectives and reliable cost estimates. Prior experience assists the contractor in preparing reliable cost estimates on new procurements for similar items or services. An exesssive cost estimate reduces the possibility that the cost of performance will exceed the contract price, therby dictating a reduction in the profit weight assigned for contract cost risk.

(iv) The third determination of the degree of cost responsibility assumed relates to the difficulty of the contractor's task. The contractor's task can be difficult or simple, regardless of the type of contract. Profit weights for contract cost risk should be adjusted accordingly.

(2) *Investment.* GSA contractors are normally encouraged to perform their contracts with the minimum of financial, facilities, or other assistance from the Government. It is the purpose of this factor to encourage the contractor to acquire and use its own resources to the maximum extent possible. The evaluation of this factor for profit weights should include an analysis of the following:

(i) *Facilities.* To evaluate how this factor contributes to the profit objective requires knowledge of the level of facilities utilization needed for contract performance, the source of financing of the required facilities, and the overall cost effectiveness of the facilities offered. Contractors who furnish their own facilities which significantly contribute to lower total contract costs should be provided with additional profit. Contractors who rely on the Government to provide or finance needed facilities should receive a corresponding reduction in profit. Situations between the above examples should be evaluated on their merits with either a positive or negative profit weight adjustment, as appropriate, being made. However, when a highly facilitized contractor is to perform a contract which does not benefit from this facilitization, or where a contractor's use of its facilities has a minimum cost impact on the contract, profit need not be adjusted.

(ii) *Payments.* In analyzing this factor, consideration should be given to the frequency of payments by the Government to the contractor. The key to this weighting is to give proper consideration to the impact the contract will have on the contractor's cash flow. Generally, negative consideration should be given for payments more frequent than monthly, with maximum reduction being given as the contractor's working capital approaches zero. Positive consideration should be given for payments less frequent than monthly with additional consideration given for payments less frequent than the contractor's or the industry's normal practice.

(3) *Performance.* A contractor's past and present performance should be evaluated in such areas as quality of product or service, meeting performance schedules, efficiency in cost control (including need for and reasonableness of cost incurred), accuracy and reliability of previous cost estimates, degree of cooperation by the contractor (both business and technical), timely processing of changes and compliance with other contractual provisions, and management of subcontract programs. Where a contractor has consistently achieved excellent results in the foregoing areas as compared with other contractors in similar circumstances, such performance merits a proportionately higher profit weight is appropriate. A poor record in this regard should be reflected by a reduced or negative weight.

(4) *Federal socio-economic programs.* This factor relates to the extent of successful participation in Government sponsored programs such as small business, small disadvantaged business, labor surplus area programs, energy conservation efforts, etc. The contractor's policies and procedures which energetically support such Government programs and achieve successful results should be given positive consideration. Failure or unwillingness on the part of the contractor to support these programs should be assigned negative profit weight consideration.

(5) *Special situations.*

(i) *Independent development.* The contractor may be provided additional profit consideration in recognition of independent development efforts relevant to the contract end item, including manufacturing or engineering processes, specialized or unique services, or other technologies. In assigning an appropriate profit weight of this factor, the contracting officer should consider the extent of the Government's contribution to the contractor's independent research and development program during the time in which the applicable development was taking place.

(ii) *Unusual pricing agreements.* Occasionally, unusual contract pricing arrangements are made with the contractor wherein it agrees to participate in the sharing of contract costs. In such circumstances, a positive profit weight may be assigned for this factor commensurate with cost savings.

(iii) *Spin-off benefits.* A negative weight may be appropriate when the contractor is expected to obtain spin-off benefits as a direct result of the contract (e.g., products with commercial application).

(f) Facilities capital cost of money. When facilities capital cost of money (cost of capital committed to facilities) is included as an item of cost in the contractor's proposal, a reduction in the profit objective shall be made in an amount equal to the amount of facilities capital cost of money allowed in accordance with §1-15.205-51(a).

(g) Nonprofit organizations.

(1) The structured approach was designed for arriving at profit or fee objectives for other than nonprofit organizations. However, if appropriate adjustments are made to reflect differences between profit and nonprofit organizations, the structured approach can be used as a basis for arriving at fee objectives for nonprofit organizations. Therefore, the structured approach, as modified in paragraph (g)(2) of this section, shall be used to establish fee objectives for nonprofit organizations. The modifications should not be applied as deductions against historical fee levels, but rather, to the fee objectives for such a contract as calculated under the structured approach.

(2) For purposes of this subparagraph, nonprofit organizations are defined as those business entities organized and operated exclusively for charitable, scientific, or educational purposes, no part of the net earnings of which inure to the benefit of any private shareholder or individual and which are exempt from Federal income taxation under Section 501 of the Internal Revenue Code.

(3) For contracts with nonprofit organizations where fees are involved, an adjustment of up to 3% will be subtracted from the total profit-fee objective. In developing this adjustment, it will be necessary to consider the following factors:

(i) Tax position benefits;

(ii) Granting of financing through letters of credit;

(iii) Facility requirements of the nonprofit organization; and

(iv) Other factors which may work to the advantage or disadvantage of the contractor in its position as a nonprofit organization.

PART 5-16 [AMENDED]

3. The table of contents for Part 5-16 is amended by adding the following:

Sec.

* * * * *

* * * * *

Authority: Sec. 205(c), 63 Stat. 390; (40 U.S.C. 486(c)).

* * * * *

Note.—The form illustrated in this § 5-16.950-1766 is filed with the original document and does not appear in this issue.

Dated: January 13, 1983.

Allan W. Beres,

Assistant Administrator for Acquisition Policy.

[FR Doc. 83-2021 Filed 1-31-83; 8:45 am]

BILLING CODE 6820-61-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

42 CFR Part 51b

Project Grants for Preventive Health Services

AGENCY: Centers for Disease Control, Public Health Service, HHS.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations in 42 CFR Part 51b which apply to grants awarded to State and local government agencies, and, in certain cases, to nonprofit entities, to assist them in implementing preventive health service programs authorized by Section 317(a) of the Public Health Service Act, and venereal disease control programs authorized by Section 318(c). This final rule adds an additional subpart to Part 51b. Subpart F is added to govern project grants for venereal disease research, demonstrations, and special public information and education under Section 318(b).

EFFECTIVE DATE: March 3, 1983.

FOR FURTHER INFORMATION CONTACT: Anthony M. Scardaci, Center for Prevention Services, Centers for Disease Control, 1600 Clifton Road NE., Atlanta, Georgia 30333, telephone (404) 329-3773 or FTS: 236-3773.

SUPPLEMENTARY INFORMATION: This final rule implements revisions proposed in a Notice of Proposed Rulemaking (NPRM) published in the **Federal Register** July 17, 1980 (45 FR 47878).

The rule implements changes made in Section 318 of the Public Health Service Act by the Health Services and Centers Amendments of 1978 (Pub. L. 95-626), approved November 10, 1978. Section 318 governs Federal assistance related to the prevention and control of venereal disease. The most significant statutory amendment requires that not less than 5 percent of funds appropriated under Section 318 be obligated to support programs authorized by Section 318(b). These programs include research, demonstrations, and public information and education activities for the prevention and control of venereal disease. Grants for support of basic venereal disease control program activities at the State and local level, except public information and education, are authorized under Section 318(c).

Since public information and education regarding venereal disease is an essential component of any federally assisted control program, these regulations permit State and local health agencies to request funds for this purpose as part of the application under Subpart D for support of other venereal disease control activities such as surveillance, contact, identification, and screening. Separate justification of an accounting for funds for public information and education activities is required, since support of the activities is authorized separately from other control program activities. The Department must be able to ensure that at least 5 percent of the funds appropriated under Section 318 generally are obligated for venereal disease research, demonstrations, or public information and education.

A new Subpart F governs grants under Section 318(b) for support of research, demonstrations, and special public information and education activities not provided through a grant made under Subpart D. Also, Subpart D is revised to reflect another amendment to Section 318 by Pub. L. 95-626 which provides for expanded professional venereal disease education, training, and clinical skills improvement activities.

The NPRM proposed a new Subpart H—Grants for Lead-Based Paint Poisoning Prevention Programs. This grant program was previously authorized under the Lead-Based Paint Poisoning Prevention Act (Pub. L. 91-695, as amended). Public Law 95-626 transferred this authority to a new Section 316 of the Public Health Service Act. Subpart H was intended to replace regulations codified at 42 CFR Part 91 and to reflect the transfer of authority, including two statutory changes. However, Subpart H is omitted from this final rule because this grant program was transferred to the Maternal and Child Health Services Block Grant by the Omnibus Budget Reconciliation Act of 1981 (Pub. L. 97-35), and the regulations at 42 CFR Part 91 were repealed effective October 1, 1982 (46 FR 48592-48593, October 1, 1981).

This final rule includes a revision of § 51b.204, Subpart B, Grants for Childhood Immunization Programs, which was not proposed in the NPRM. Section 51b.204 has been revised for clarity and to state the program elements more specifically. This revision is not a change in current requirements. In addition, the revision distinguishes between the information required in the initial application covering the project period and information required in the application required annually for the budget period. The purpose is to reduce the burden imposed on applicants in completing grant applications by specifying the minimum information necessary to enable CDC to administer the program and meet the statutory requirements of the Act. Similar clarification has been added under the application requirements for § 51b.405, Subpart D, and § 51b.604, Subpart F.

Attention is called to two other changes made in the final rule. The first is the transfer to § 51b.103(c), Subpart A, General Provisions, of the provision currently contained in § 51b.204(d)(3) of Subpart B and § 51b.405(a)(9) of Subpart D. The provision requires grantee assurances that no one will be denied services because of inability to pay, and that services will be provided in a manner which preserves human dignity and maximizes acceptance of the program. The provision is applicable to all programs under Part 51b and, therefore, should be in the General Provisions in Subpart A. The second change is the omission in the final rule of the provision in § 51b.405(b), Subpart D, of the NPRM which required that a rate schedule for any third party reimbursements be submitted with the application for approval, and that confidentiality of patient records be protected in any billing arrangements. These requirements were omitted in the final rule because they are unnecessarily burdensome, and confidentiality requirements related to venereal disease control are currently contained in § 51b.404, Subpart D.

Comments

Comments were received from only one source in response to the NPRM. One comment suggested adding language under § 51b.106(e) indicating that if additional conditions are imposed by the Secretary, additional funding would be provided. In response, additional conditions included in an award notice as used in this context normally means limitations or requirements of an administrative nature. They do not generally establish requirements of a program operation nature that would require additional resources. If there are required activities which the applicant has not included in the project plan and for which grant funds are available, the applicant would be required to amend the grant application before an award notice would be issued.

Another comment related to venereal disease grants stated that the provision in § 51b.405(a)(7)(i), "to be served with special reference to those federally assisted programs (for example, community health centers, family planning clinics, and migrant health programs)," be deleted until the Secretary can provide a detailed up-to-date list of federally assisted programs related to venereal disease control in given geographic areas. All of the provisions enumerated as § 51b.405(a)(7) in the NPRM have been deleted.

Another comment, in regard to venereal disease grants, suggested deletion of the requirement for a separate itemization and justification of funds for public information and education activities under § 51b.405(a)(8). The commenter believes this provision represents a duplicative and undue paperwork burden on the applicant since a separate budget and justification are required for programs regulated by Subpart F. In response, the requirement under Subpart D, § 51b.405(8), that "public information and education activities * * * must be itemized and justified separately" is for the purpose of relieving applicants for funds under Subpart D (States and large cities) of the need to submit a separate project application for venereal disease public information and education activities, while at the same time permitting the Secretary to ensure that at least 5 percent of funds appropriated under Section 318 are used to support research, demonstrations, and public information and education as required by law.

Another comment, applicable to Subpart D, § 51b.407, recommended deletion of the restrictions on use of funds for diagnosis, treatment, and data processing equipment. The commenter believes that the provision is too cumbersome and restrictive, and that applicants should have flexibility to deal with the situations which they have had to justify already in the application. In response, the provision is not intended to forbid use of grant funds for these situations, but only to require advance approval. It is intended that the grant program supplement the efforts of State and local health agencies rather than supplanting activities which they would normally provide.

The requirements of the Regulatory Flexibility Act do not apply to these regulations since the Notice of Proposed Rulemaking was issued prior to January 1, 1981, the effective date of the Act. Nevertheless, the Secretary believes this rule will not have a significant economic impact on a substantial number of small entities. Further, the Secretary has determined that the costs associated with this regulation are negligible, and therefore a regulatory impact analysis is not required under Executive Order 12291.

The Department was required to submit to the Office of Management and Budget (OMB) for review and approval §§ 51b.103, .105, .204, .405, and .604 of the regulations which deal with reporting and/or recordkeeping requirements. The reporting requirements in all of these sections have now been approved by OMB (OMB approval Numbers 0937-0011, 0920-0110, and 0920-0112).

List of Subjects in 42 CFR 51b

Communicable diseases, Grant programs—health immunization, Maternal and child health, Venereal diseases.

Accordingly, Part 51b of Title 42 is amended as set forth below.

(Catalog of Federal Domestic Assistance (CFDA) numbers which have been assigned to programs governed by Part 51b are as follows:

Subpart B—Grants for Childhood Immunization Programs, CFDA—13.268.
Subpart D—Grants for Venereal Disease Control Programs, CFDA—13.977.
Subpart F—Grants for Research, Demonstrations, and Public Information and Education for the Prevention and Control of Venereal Disease, CFDA—13.978.)

Dated: September 2, 1982.

Edward N. Brandt, Jr.,
Assistant Secretary for Health.

Approved: December 16, 1982.

Richard S. Schweiker,
Secretary.

PART 51b—[AMENDED]

42 CFR Part 51b is amended as follows:

1. The table of sections for Subpart A and Subpart D are revised, a table of sections is added for the new Subpart F, and the authority citation is revised as follows:

Subpart A—General Provisions

* * * * *

Subpart D—Grants for Venereal Disease Control Progams

* * * * *

Subpart F—Grants for Research, Demonstrations, and Public Information and Education for the Prevention and Control of Venereal Disease

* * * * *

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

2. Subpart A is revised to read as follows:

Subpart A—General Provisions

§ 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:

"Act" means the Public Health Service Act, as amended.

"Secretary" means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.

"State" means one of the 50 States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

§ 51b.103 What are the general application requirements?

(a) The project application shall contain a full description of the program objectives, plans, and activities. With respect to programs authorized by Section 317 of the Act only, the application shall also provide, as the Secretary may require:

(1) The amount of Federal, State, and other funds obligated by the applicant in its latest annual accounting period for the provision of such program.

(2) A description of the services provided by the applicant for this accounting period covered under subparagraph (1) above.

(3) The amount of Federal funds needed by the applicant to continue providing these services.

(4) A description of any proposed changes in the provision of the services, reasons and priorities, and the amount of Federal funds needed by the applicant to make the changes.

(b) The application shall contain evidence satisfactory to the Secretary that it has been submitted, as appropriate, for action to the planning agency designated by the Secretary under Title XV of the Act (42 CFR Parts 122 and 123). These grants are subject to the intergovernmental review of Federal programs of Executive Order 12372.

(c) The application shall contain assurances that no one will be denied services because of inability to pay, and that the services are provided in a manner which preserves human dignity and maximizes acceptance.

§ 51b.104 Can personnel, supplies, and related items be provided in lieu of cash?

The Secretary may reduce a grant by the amount of the fair market value of any supplies (including vaccines and other preventive agents) or equipment furnished a grant recipient when furnished at the request of the recipient. The Secretary also may reduce a grant by the amount of the pay, allowances, travel expenses, and any other costs in connection with the detail of any officer or employee of the Government to the recipient when the detail is at the request of the recipient. The amount the grant is reduced shall be available for payment by the Secretary of the costs incurred in furnishing the supplies or equipment or in detailing personnel and shall be deemed to have been paid to the recipient.

§ 51b.105 Which other HHS regulations apply to these grants?

Several other HHS regulations apply to grants under this part. These include, but are not limited to:

42 CFR Part 50—PHS grant appeals procedure
45 CFR Part 16—Department grant appeals process
45 CFR Part 46—Protection of human subjects
45 CFR Part 74—Administration of grants
45 CFR Part 75—Informal grant appeals procedures (indirect cost rates and other cost allocations)
45 CFR Part 76—Debarment and suspension from eligibility for financial assistance
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
45 CFR Part 83—Regulation for the administration and enforcement of Sections 704 and 855 of the PHS Act
45 CFR Part 84—Nondiscrimination on the basis of handicap in federally assisted programs
45 CFR Part 86 and Appendix A—Nondiscrimination on the basis of sex in federally supported education programs
45 CFR Part 90—Nondiscrimination on the basis of age in programs or activities receiving Federal financial assistance.

§ 51b.106 What other conditions apply to these grants?

(a) The notice of grant award specifies how long HHS intends to support the project without requiring the project to recompete for funds. This period, called the project period, will usually be for 2 to 5 years.

(b) For budgetary and funding purposes, the project period is generally divided into 12-month intervals called budget periods. A grantee must submit a separate application to have the support continued for each subsequent budget period after the initial award. Decisions regarding continuation awards and the funding level of such awards will be made after consideration of such factors as the grantee's progress and management practices and the availability of funds. In all cases, continuation awards require a determination by HHS that continued funding is in the best interest of the government.

(c) Neither the approval of any application nor the award of any grant commits or obligates the United States in any way to make any additional, supplemental, continuation, or other award with respect to any approved application or portion of an approved application.

(d) Any funds granted pursuant to this subpart shall be expended solely for the purposes for which the funds were granted in accordance with the approved application and budget, the regulations of this part, the terms and conditions of the award, and the applicable cost principles prescribed in Subpart Q of 45 CFR Part 74.

(e) The Secretary may, at the time of award, impose additional conditions, including conditions governing the use of information or consent forms, when, in the Secretary's judgment, they are necessary to advance the approved program, the interest of the public health, or the conservation of grant funds.

§ 51b.107 Is participation in preventive health service programs required by these regulations?

Nothing in these regulations shall be construed to require any State or political subdivision to have a preventive health service program which would require any person who objects to treatment to be treated under the program.

3. Subpart B, § 51b.204 is revised to read as follows:

§ 51b.204 What information is required in the application?

(a) The initial application must cover the project period, and must include a description of the following:

(1) The need for grant support.

(2) The immediate (1 year budget period) and long-range (2–5 year project period) objectives of the project in specific and measurable terms.

(3) Current immunization programs and the additional or intensified activities to be carried out to meet the objectives and priorities.

(4) The following program elements should be included and described:

(i) A plan to assure that children begin and complete their immunizations on schedule, including the use of a standard immunization record card, a provider-based tickler system (public and private) for the recall of children, and a hospital-based immunization education program for new mothers.

(ii) Assessment of immunization status of school enterers, children attending licensed day-care centers, and children under 2 years of age and new enrollees under age 5 served in public clinics.

(iii) A plan for surveillance of vaccine-preventable diseases that includes morbidity and mortality reporting as well as field and laboratory investigations.

(iv) Procedures for prompt review of the data collected from the morbidity surveillance system to allow for immediate response to all occurrence of suspected diphtheria and polio cases upon notification and response to suspected measles cases within 48 hours.

(v) A system for monitoring vaccine-associated reactions including a mechanism for responding to persons with vaccine-related complaints.

(vi) A plan to systematically immunize susceptible children at school entry through vigorous enforcement of school immunization laws.

(5) The manner in which the applicant intends to evaluate the project.

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

(1) A budget and justification for the grant funds requested.

(2) A summary of the progress achieved during the previous budget period.

(3) A description of any changes in the information shown in the project application.

§ 51b.205 [Amended]

4. Subpart B, § 51b.205 is amended by removing paragraph (c).

5. Subpart D is revised to read as follows:

Subpart D—Grants for Venereal Disease Control Programs

§ 51b.401 To which programs does this subpart apply?

The regulations in this subpart apply to the award of project grants under Section 318(c) of the Act for venereal disease prevention and control programs, and under Section 318(b) of the Act with respect to public information and education activities which are integral to a balanced, comprehensive venereal disease control program.

§ 51b.402 Definitions.

As used in this subpart:

"Venereal disease" means gonorrhea, syphilis, or any other disease which can be sexually transmitted and which the Secretary determines is or may be amenable to control with assistance provided under this authority and which is of national significance.

"Venereal disease control program" means a program designed to carry out activities or to provide services to systematically detect and prevent venereal disease as distinguished from those activities or services which are designed to diagnose or treat venereal disease patients or suspects.

§ 51b.403 Who is eligible for a grant under this subpart?

An applicant must be a State agency or a political subdivision of a State which has legal responsibility for disease control under the laws of the State.

§ 51b.404 What are the confidentiality requirements?

All information obtained by program personnel in connection with the examination, care, and treatment of an individual in this program shall be held confidential. It shall not be disclosed without the individual's consent except as may be required by the law of a State or political subdivision of a State or as may be necessary to provide services to the individual. Information may be disclosed in summary, statistical, or other form, or for clinical or research purposes, but only if the disclosure does not identify particular individuals.

§ 51b.405 What information is required in the application?

(a) The initial application must include a description of the following:

(1) The nature and extent of the venereal disease problem in the area.

(2) The need for project grant support.

(3) The immediate (1-year budget period) and long-range (2–5 year project period) objectives of the project in specific and measurable terms.

(4) The activities to be carried out to meet the objectives. The following program elements must be included and described:

(i) Venereal disease surveillance.

(ii) Casefinding and case followup.

(iii) Interstate epidemiologic referral and followup.

(iv) Public venereal disease information and education.

(v) Professional (including appropriate allied health personnel) venereal disease education, training, and clinical skills improvement activities, including efforts to assure high quality clinical services in public venereal disease clinics.

(5) At the option of the applicant, special studies or demonstrations to evaluate or test venereal disease prevention and control strategies and activities.

(6) The manner in which the applicant intends to conduct and evaluate the project, including a system for analysis of morbidity data so that control activities can be efficiently evaluated and targeted.

(7) The diagnostic and treatment services that will be provided.

(8) A budget and justification for the grant funds requested. Since public information and education activities are authorized separately from other control program activities, funds requested for this purpose must be itemized and justified separately in the narrative part of the application.

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

(1) A budget and justification for the grant funds requested.

(2) A summary of the progress achieved during the previous budget period.

(3) A description of any changes in the information shown in the project application.

§ 51b.406 How will grant applications be evaluated and the grants awarded?

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting the cost of a venereal disease control program. Before awarding a grant to a political subdivision of a State, the Secretary will consult with the State health authority.

(b) Priorities for funding will be based on the following factors:

(1) The relative extent of the venereal disease problem in the area served by the applicant.

(2) The design of the venereal disease prevention and control program.

(3) The general quality of the applicant's plan of operation and objectives in accordance with the requirements in these regulations. Emphasis will be placed on determining the extent to which services are coordinated among health care providers in the area served and integrated into a cohesive plan for delivery of service to groups having the highest incidence of venereal disease.

(4) The capacity of the applicant to make effective use of Federal funds.

(5) The commitment of the applicant to the control of venereal disease as reflected in the commitment of applicant resources to the program.

§ 51b.407 How can grant funds be used?

Grant funds awarded under this subpart may be used only for programs approved under Section 318(c), and with respect to public information and education, those programs approved under Section 318(b) of the Act. Unless specifically approved, grant funds shall not be used for performing diagnostic tests (other than gonorrhea screening tests), maintaining central registries, purchasing data processing equipment, or providing diagnostic and treatment facilities and services. The applicant must provide assurances, however, that these services will be available as needed as an adjunct to control program activities supported with grant funds. To obtain special approval for grant support of such activities, the grantee shall justify the exception to the satisfaction of the Secretary that funds for this purpose are necessary for the proper conduct of the program and are otherwise unavailable. Support of these services will generally be approved only in the following situations: (a) Special studies or demonstrations, (b) the support of developmental or start-up activity, or (c) the support of an essential service which will result in a savings to a detection or prevention activity supported by the grant. Unless otherwise approved, exceptions based on paragraphs (b) and (c) of this section are only allowed during one funding period. The grantee is expected to support these activities in subsequent funding periods.

6. Subpart F is added to Part 51b as follows:

Subpart F—Grants for Research, Demonstrations, and Public Information and Education for the Prevention and Control of Venereal Disease

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

The regulations in this subpart apply to the award of venereal disease control project grants for research, demonstrations, public information, and education activities which can be applied to achieve improvements in venereal disease prevention and control under Section 318(b) of the Act.

§ 51b.602 Who is eligible for a grant under this subpart?

An applicant must be a State, political subdivision of any State, or any other public or nonprofit private entity.

§ 51b.603 What are the confidentiality requirements?

All information obtained by program personnel in connection with the examination, care, and treatment of an individual in this program shall be held confidential. It shall not be disclosed without the individual's consent except as may be required by the law of a State, or political subdivision of a State, or as may be necessary to provide services to the individual. Information may be disclosed in summary, statistical, or other form, or for clinical or research purposes, but only if the disclosure does not identify particular individuals.

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

(a) The initial application must include a description of the following:

(1) The setting and circumstances for which project grant support is being requested, including:

(i) The immediate and long-range objectives of the project in specific and measurable terms.

(ii) The activities which will be undertaken to accomplish the objectives, including the timing of these activities.

(iii) The anticipated application of findings to the national venereal disease control effort.

(iv) Any other information which will support the request for grant assistance.

(2) The relationship between the planned activities and the project objectives. The application must describe in detail how the applicant intends to proceed, particularly if the project is unusually complex and several activities are interdependent or unprecedented.

(3) A comprehensive and realistic plan which the applicant will use to evaluate the project. The plan must include periodic assessment of any possible impact, both positive and negative, that the proposed project might have upon the established venereal disease control program in the locality or localities in which the project will be undertaken.

(b) An application for a continuation grant must be submitted for each funding period. This continuation application must include the following:

(1) A budget and justification for the grant funds requested.

(2) A summary of the progress achieved during the previous budget period.

(3) A description of any changes in the information shown in the project application.

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

(a) Within the limits of funds available, the Secretary may award a grant to assist in meeting the costs of special activities authorized under Section 318(b) of the Act.

(b) Grant applications will be reviewed and evaluated according to the following criteria:

(1) Is there adequate evidence that the proposed project is needed and that the outcome has potential to directly benefit the national venereal disease control effort?

(2) Are the project objectives specific, measurable, realistic, time phased, and related to promoting the purposes of Section 318?

(3) Is the method of operation logical and clearly related to project objectives, and does it describe how the applicant intends to proceed particularly with activities which are complex, interrelated, or unprecedented?

(4) Does the method of operation include an assessment of any possible impact, both positive and negative, that the conduct of the proposed initiative might have upon the established venereal disease control program in the locality or localities in which the project will be undertaken?

(5) Does the proposal include a comprehensive and realistic plan for the evaluation of the project, and specify the measures and instruments of measurement to be used?

(6) Is the budget request reasonable and consistent with the intended use of grant funds?

(7) If the applicant intends only to evaluate an existing disease prevention and control approach, are the objectives substantially different from those which could be met by routine program evaluation?

§ 51b.606 How can grant funds be used?

(a) Grant funds may be used for the costs associated with planning, organizing, and conducting applied research, demonstrations, and public information and education programs.

(b) Grant funds may also be used to reimburse individuals who agree to be participants in the applied research projects. This reimbursement, however, must be justified as necessary and reasonable. A schedule of reimbursements must be submitted with the application and approved as part of the program plan.

(c) Grant funds may not be used to supplant funds supporting existing venereal disease control services provided by a State or locality.

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