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take into account, among other pertinent factors:

(1) The significance from a scientific or technical standpoint of the goals of the proposed research or development activity;

(2) The availability of the technology and other resources necessary to achieve those goals;

(3) The extent to which there are identified, practical uses for the anticipated results of the activity; and

(4) Where the review includes the project approach, the adequacy of the methodology to be utilized in carrying out the activity.

(b) In carrying out its review of unsolicited contract proposals under §52h.9, the peer review group shall take into account, among other pertinent factors, the criteria in §52h.8 which are relevant to the particular proposals.

(c) In carrying out its review of solicited proposals under §52h.10(a) or (b), the peer review group shall evaluate each proposal in accordance with the criteria set forth in the request for proposals.

§ 52h.12 Other regulations that apply.

The regulations in this part are in addition to, and do not supersede other regulations concerning grant applications, contract projects, or contract proposals set forth elsewhere in this title, title 45, or title 48 of the Code of Federal Regulations.
all patients regardless of the source of payment for such care: And provided further, That in determining such operating costs there shall be deducted the amount of all actual or estimated reimbursements, as applicable, for services received or to be received pursuant to title XVIII and XIX of the Social Security Act (42 U.S.C. 1395 and 1936);

(5) The term reasonable cost means the cost of providing services to a specific patient determined in accordance with the cost determination principles and requirements under title XVIII of the Social Security Act (42 U.S.C. 1395) and subpart D of the regulations thereunder (20 CFR part 405, 1 part 401 seq.);

(6) The term uncompensated services means services which are made available to persons unable to pay therefor without charge or at a charge which is less than the reasonable cost of such services. The level of such services is measured by the difference between the amount charged such persons for such services and the reasonable cost thereof;

(7) Reasonable volume of services to persons unable to pay therefor means a level of uncompensated services which meets a need for such services in the area served by an applicant and which is within the financial ability of such applicant to provide.

(c) Assurance. (1) Before an application under this part is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor. The requirement of an assurance from an applicant shall be waived if the applicant demonstrates to the satisfaction of the State agency that there will be made available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor. The requirement of an assurance from an applicant shall be waived if the applicant demonstrates to the satisfaction of the State agency that such a requirement is not feasible from a financial viewpoint.

(2) Prior to recommending that such requirement be waived, the State agency shall publish in a newspaper of general circulation in the area served by the applicant a notice of the request for such waiver and invite public comment thereon, allowing not less than 30 days therefor. All comments received shall be available for public inspection, and shall be considered by the State agency in arriving at its recommendation. Notice of the determination on the request for waiver shall be given to all interested persons and to the public before the approval of the Secretary is sought.

(d) Presumptive compliance guideline. An applicant which, for a fiscal year, (1) budgets for the support of, and makes available on request, uncompensated services at a level not less than the lesser of 3 percent of operating costs or 10 percent of all Federal assistance provided to or on behalf of the applicant under the Act, or (2) certifies that it will not exclude any person from admission on the ground that such person is unable to pay for needed services and that it will make available to each person so admitted services provided by the facility without charge or at a charge below reasonable cost which does not exceed any such person’s ability to pay therefor as determined in accordance with criteria established pursuant to paragraph (g), shall be deemed in presumptive compliance with its assurance. In the case of a loan guarantee with interest subsidy or a direct loan guarantee be sold by the Secretary with an interest subsidy, the amount of Federal assistance shall include the total amount of the interest subsidy which the Secretary is, or will be, obligated to pay over the full life of the loan, as well as any other payments which the Secretary makes on behalf of the applicant in connection with the loan guarantee or the direct loan which has been sold.

(e) Compliance reports. (1) Each applicant shall, not later than 120 days after the end of a fiscal year, unless a longer period is approved by the State agency for good cause shown, file with the State agency a copy of its annual statement for such year as required by section 646 of the Act and §53.128(q), which shall set forth its operating costs.

(2) With respect to each fiscal year for which a level of uncompensated services has been established in accordance with this section, the annual

1Redesignated as 42 CFR part 405 at 42 FR 52826, Sept. 30, 1977.
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Statement shall also set forth the amount of uncompensated services provided in such year.

(i) The provision of a level of uncompensated services in such year which equals or exceeds the level established pursuant to paragraph (h) of this section for such year shall constitute compliance with the assurance.

(ii) If the level of services provided was less than the level of uncompensated services established pursuant to paragraph (h) of this section, the applicant shall submit with such statement: A justification therefor, showing that the provision of such lower level of uncompensated services was reasonable under the circumstances; and a description of the steps it proposes to take to assure the availability and utilization of the level of uncompensated services to be established for the current fiscal year, which shall include an affirmative action plan, utilizing press releases or other appropriate means as the facility may desire to bring to the attention of the public the availability of such uncompensated services and the conditions of eligibility therefor.

(3) Each applicant shall file with its annual statement a copy of that portion of its adopted budget for the current fiscal year relating to the support of uncompensated services in such year. Such budget for uncompensated services shall be based on the operating costs of the applicant for the preceding fiscal year and shall give due cognizance to probable increases in operating costs. Except in the case of a certification pursuant to paragraph (d)(2) of this section, if the budget statement does not conform to the presumptive compliance guideline, the applicant shall submit with its statement:

(i) A justification therefor, showing that such lower level of uncompensated services is reasonable under the circumstances, and

(ii) A plan to increase such uncompensated services to meet the presumptive compliance guideline or such other level of uncompensated services as may have been established or as it requests the State agency to establish in accordance with paragraph (h) of this section.

(4) The applicant shall also submit such additional reports related to compliance with its assurance as the State agency may reasonably require.

(5) Pending the establishment of a level of uncompensated services for any fiscal year pursuant to paragraph (h) of this section, the applicant shall, in such fiscal year, provide a level of services which is the higher of

(i) The level established for the preceding fiscal year (or if no such level has been established for such prior year, the level of services provided in such year) or

(ii) The level proposed in its adopted budget for the current fiscal year.

(f) Qualifying services. (1) In determining the amount of uncompensated services provided by an applicant, there shall be included only those services provided to an individual with respect to whom the applicant has made a written determination prior to the provision of such services that such individual is unable to pay therefor under the criteria established pursuant to 42 CFR 53.111(g), except that:

(i) Such determination may be made after the provision of such services in the case of services provided on an emergency basis: Provided. That when billing is made for such service, such billing must be accompanied by substantially the information required in the posted notice under paragraph (i) of this section; and

(ii) Such determination may be made after the provision of such services in the case of a change in circumstances as a result of the illness or injury occasioning such services (e.g., the patient’s financial condition has changed due to a loss of wages resulting from the illness) or in case of insurance coverage or other resources being less than anticipated or the costs of services being greater than anticipated. Further, in all cases where such determination was not made prior to the provision of services, such services may not be included as uncompensated services if any collection effort has been made other than the rendering of bills permissible in the above exceptions: Provided. That such a determination may be made at any time if the determination was hindered or delayed by reason of erroneous or incomplete information furnished by or in behalf of the patient.
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(2) There shall be excluded from the computation of uncompensated services:

(i) Any amount which the applicant has received, or is entitled to receive, from a third party insurer or under a governmental program; and

(ii) The reasonable cost of any services for which payment in whole or in part would be available under a governmental program (e.g., Medicare and Medicaid) in which the applicant, although eligible to do so, does not participate, but only to the extent of such otherwise available payment.

(g) Persons unable to pay for services.

(1) The State agency shall set forth in its State plan, subject to approval by the Secretary, criteria for identifying persons unable to pay for services, which shall include persons who are otherwise self-supporting but unable to pay the full charge for needed services. Such criteria shall be based on the following or similar factors:

(i) The health and medical care insurance coverage, personal or family income, the size of the patient’s family, and other financial obligations and resources of the patient or the family in relation to the reasonable cost of the services;

(ii) Generally recognized standards of need such as:

(a) The State standard for the medically needy as determined for the purposes of the Aid for Families with Dependent Children program;

(b) The current Social Security Administration poverty income level;

(c) The current Office of Economic Opportunity Income Poverty Guidelines applicable in the area; or

(iii) Any other equivalent measures which are found by the Secretary to provide a reasonable basis for determining an individual’s ability to pay for medical and hospital services.

(2) A copy of such criteria shall be provided by the applicant, upon request, to any patient or former patient of the applicant and to any person seeking services from the applicant.

(3) The State agency shall provide a copy of such criteria to any person requesting it.

(h) Level of uncompensated services.

(1) The State agency shall set forth in its State plan procedures for the determination for each applicant of the level of uncompensated services which constitutes a reasonable volume of services to persons unable to pay therefore provided that in no event shall the level of uncompensated services established under this section exceed the presumptive compliance guideline.

(2) The State agency shall for the purpose of making such determination, review, and evaluate the annual statement, the budget and the related documents submitted by each applicant pursuant to paragraph (e) of this section, by applying the following criteria:

(i) The financial status of the applicant, taking account of income from all sources, and its financial ability to provide uncompensated services;

(ii) The nature and quantity of services provided by the applicant;

(iii) The need within the area served by the applicant for the provision, without charge or at charge which is less than reasonable cost, for services of the nature provided or to be provided by the applicant; and

(iv) The extent and nature of joint or cooperative programs with other facilities for the provision of uncompensated services, and the extent and nature of outreach services directed to the needs of underserved areas.

(3) In accordance with its findings made after such review and evaluation, the State agency shall, within 60 days after receipt of the annual statement and related documents required by paragraph (e) of this section, for each fiscal year of an applicant which begins following the expiration of 90 days after the effective date of this regulation:

(i) Establish a level of uncompensated services for each applicant which may be equal to or less than the presumptive compliance guideline: Provided, That if the State agency determines, in accordance with paragraph (h)(2) of this section, that (a) there is a need in the area served by an applicant for a level of uncompensated services greater than the level proposed in the applicant’s budget statement, and (b) the applicant is financially able to provide such greater level of uncompensated services, the State agency shall
establish such greater level as the level applicable to the applicant; and

(ii) Accept or modify a plan submitted pursuant to paragraph (e) of this section.

(4) The State agency shall notify the applicant in writing of the level of uncompensated services which it has established for the applicant for the fiscal year. At the time of notifying the applicant, the State agency shall also publish as a public notice in a newspaper of general circulation within the community served by the applicant the rate that has been established and a statement that the documents upon which the agency based its determination are available for public inspection at a location and time prescribed. In the case of the establishment by the State agency of a rate which is less than the presumptive compliance guideline, such notice shall also include a statement that persons wishing to object to the rate established may do so by writing to the State agency within 20 days after publication of the notice: Provided, That the applicant may object to any level established which is greater than the level proposed in the applicant’s budget statement.

(5) In accordance with the provisions of paragraph (h)(4) of this section, the applicant or any person or persons residing or located within the area served by the applicant, or any organization on behalf of such person or persons, may submit to the State agency within 20 days of the publication and sending of the notice objections to the rate established by the State agency for the applicant. Such objections may be supported in writing by factual information and argument. The State agency shall give public notice of receipt of the objections and shall make the objections and their supporting documents available for public inspection and comment. It may, if it believes that determination of the objections will be assisted by oral evidence or by oral argument, set a public hearing on the objections and shall give notice of such hearing to all interested parties and to the public. The State agency shall within 60 days of the expiration of the period within which objections may be filed, rule upon the objections in writing, stating its reason for sustaining or overruling them, in whole or in part, and establishing finally the rate of uncompensated services either the same as, above, or below the rate previously established, as may best accord with all of the evidence on file with or heard by the State agency. Notice of the final determination shall be mailed to all parties who filed objections or who participated in the proceedings leading to the redetermination.

(6) Within 20 days of receipt of written notice of the final determination of a State agency after ruling on objections to the rate established by the State agency, the applicant or any other interested person or organization may submit to the Secretary a written request for review of the State agency determination. Such review shall be made upon the record of the State agency determination which shall be sustained if supported by substantial evidence and is not otherwise arbitrary or capricious. If the Secretary or his designee determines that the rate established by the State agency is unsupported by the evidence in the record or is otherwise arbitrary or capricious, the Secretary or his designee shall, upon the basis of the record or upon other evidence or information which is before him or which he may obtain, establish a level of uncompensated services which he determines, in accordance with the criteria set out in paragraph (h)(2) of this section, is appropriate.

(7) The level of uncompensated services established for an applicant under this section for any fiscal year shall constitute a reasonable volume of services to persons unable to pay therefor with respect to such applicant for such fiscal year.

(i) Posted notice. The applicant shall post notice (which shall be multilingual where the applicant serves a multilingual community), in substantially the following form, in appropriate areas within the facility (admissions, office, emergency department and business office) for the purpose of informing patients or potential patients that criteria for eligibility and applications are available upon request:
NOTICE OF HILL-BURTON OBLIGATION

This hospital (or other facility) is required by law to give a reasonable amount of service at no cost or less than full cost to people who cannot pay. If you think that you are eligible for these services, please contact our business office (give office location) and ask for assistance. If you are not satisfied with the results, you may contact (the State Hill-Burton agency with address).

Provided, That an applicant which has selected a presumptive compliance guideline under paragraph (d)(1) of this section may, at its option, either (1) add to such notice language stating that the facility’s obligation is limited to a specified dollar volume of uncompensated services and that if the facility has, during a specified period (e.g., year, quarter, month), already provided a volume of uncompensated services sufficient to satisfy such obligation, any person inquiring about such services will be given a written statement to that effect which shall also state when additional uncompensated services will be available; or (2) post an additional notice stating that the facility’s obligation has been satisfied for the current period and stating when additional uncompensated services will be available.

(j) Evaluation and enforcement. The State plan shall provide for evaluation and enforcement of the assurance in accordance with the following requirements:

(1) The State agency shall,
   (i) At least annually, perform evaluations of the amount of the various services provided in each facility with respect to which Federal assistance has been provided under the Act, to determine whether such assurance is being complied with; and
   (ii) Establish procedures for the investigation of complaints that such assurance is not being complied with.

(2) Evaluation pursuant to paragraph (j)(1) of this section shall be based on the annual budget of each facility for uncompensated services and on financial statements of such facilities filed pursuant to section 646 of the Act and §53.128(q), and on such other information, including reports of investigations and hearing decisions, as the State agency deems relevant and material.

(3) The State plan shall provide for adequate methods of enforcement of the assurance, including effective sanctions to be applied against any facility which fails to comply with such assurance. Such sanctions may include, but need not be limited to, license revocation, termination of State assistance, and court action.

(k) Reports. (1) The State agency shall, not less often than annually, report in writing to the Secretary its evaluation of each facility’s compliance with the assurance, the disposition of each complaint received by the State agency, proposed remedial action with respect to each facility found by the State agency to be not in compliance with the assurance, and the status of such remedial action.

(2) In addition, the State agency shall promptly report to the Regional Attorney and Regional Health Director of the Department of Health and Human Services the institution of any legal action against a facility or the State agency involving compliance with the assurance.


§ 53.112 Nondiscrimination.

(a) Before an application is recommended by a State agency to the Secretary for approval, the State agency shall obtain an assurance from the applicant that all portions and services of the entire facility for the construction or modernization of which, or in connection with which, aid under the Act is sought will be made available without discrimination on account of creed and no professionally qualified person will be discriminated against on account of creed with respect to the privilege of professional practice in the facility.

(b) Each construction contract is subject to the condition that the applicant shall comply with the requirements of Executive Order 11246, September 24, 1965 (30 FR 12319), relating to nondiscrimination in construction contract employment, and the applicable rules, regulations, and procedures prescribed pursuant thereto.

(c) Attention is called to the requirement of title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d; 78 Stat. 252) which provides that no person in the United States shall, on the ground of race, color, or national origin be excluded from participation in, be denied