

SUBCHAPTER K—HEALTH RESOURCES DEVELOPMENT

PART 121—ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

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AUTHORITY: Sections 215, 371–376 of the Public Health Service Act (42 U.S.C. 216, 273–274d); sections 1102, 1106, 1138 and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1320b–8 and 1395hh); and section 301 of the National Organ Transplant Act, as amended (42 U.S.C. 274e).

SOURCE: 63 FR 16332, Apr. 2, 1998, unless otherwise noted.

§ 121.1 Applicability.

(a) The provisions of this part, with the exception of § 121.13, apply to the operation of the Organ Procurement and Transplantation Network (OPTN) and to the Scientific Registry.

(b) The provisions of § 121.13 apply to the prohibition set forth in section 301 of the National Organ Transplant Act, as amended.

(c) In accordance with section 1138 of the Social Security Act, hospitals in which organ transplants are performed and which participate in the programs under titles XVIII or XIX of the Social Security Act, and organ procurement organizations designated under section 1138(b) of the Social Security Act, are subject to the requirements of this part.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999; 72 FR 10618, Mar. 9, 2007]

§ 121.2 Definitions.

As used in this part—

Act means the Public Health Service Act, as amended.

Designated transplant program means a transplant program that has been found to meet the requirements of § 121.9.

Family member means a family member of a transplant candidate, transplant recipient, or organ donor.

OPTN computer match program means a set of computer-based instructions which compares data on a cadaveric organ donor with data on transplant candidates on the waiting list and ranks the candidates according to OPTN policies to determine the priority for allocating the donor organ(s).

Organ means a human kidney, liver, heart, lung, pancreas, or intestine (including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract). Blood vessels recovered from an organ donor during the recovery of such organ(s) are considered part of an organ with which they are procured for purposes of this part if the vessels are intended for use in organ transplantation and labeled “For use in organ transplantation only.”

Organ donor means a human being who is the source of an organ for transplantation into another human being.

Organ procurement organization or *OPO* means an entity so designated by the Secretary under section 1138(b) of the Social Security Act.

Organ procurement and transplantation network or *OPTN* means the network established pursuant to section 372 of the Act.

Potential transplant recipient or *potential recipient* means a transplant candidate who has been ranked by the OPTN computer match program as the person to whom an organ from a specific cadaveric organ donor is to be offered.

Scientific Registry means the registry of information on transplant recipients established pursuant to section 373 of the Act.

Secretary means the Secretary of Health and Human Services and any official of the Department of Health and Human Services to whom the authority involved has been delegated.

Transplant candidate means an individual who has been identified as medically suited to benefit from an organ transplant and has been placed on the waiting list by the individual's transplant program.

Transplant hospital means a hospital in which organ transplants are performed.

Transplant physician means a physician who provides non-surgical care and treatment to transplant patients before and after transplant.

Transplant program means a component within a transplant hospital which provides transplantation of a particular type of organ.

Transplant recipient means a person who has received an organ transplant.

Transplant surgeon means a physician who provides surgical care and treatment to transplant recipients.

Waiting list means the OPTN computer-based list of transplant candidates.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999; 72 FR 10619, Mar. 9, 2007; 72 FR 10925, Mar. 12, 2007]

§ 121.3 The OPTN.

(a) *Organization of the OPTN.* (1) The OPTN shall establish a Board of Directors of whatever size the OPTN determines appropriate. The Board of Directors shall include:

(i) Approximately 50 percent transplant surgeons or transplant physicians;

(ii) At least 25 percent transplant candidates, transplant recipients, organ donors and family members. These members should represent the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN including, to the extent practicable, the minority and gender diversity of this population. These members shall not be employees of, or have a similar relationship with OPOs, transplant centers, voluntary health organizations, transplant coordinators, histocompatibility experts, or other non-physician transplant profes-

sionals; however, the Board may waive this requirement for not more than 50 percent of these members; and

(iii) Representatives of OPOs, transplant hospitals, voluntary health associations, transplant coordinators, histocompatibility experts, non-physician transplant professionals, and the general public.

(2) The Board of Directors shall elect an Executive Committee from the membership of the Board. The Executive Committee shall include at least one general public member, one OPO representative, approximately 50 percent transplant surgeons and transplant physicians, and at least 25 percent transplant candidates, transplant recipients, organ donors, and family members.

(3) The Board of Directors shall appoint an Executive Director of the OPTN. The Executive Director may be reappointed upon the Board's determination that the responsibilities of this position have been accomplished successfully.

(4) The Board of Directors shall establish such other committees as are necessary to perform the duties of the OPTN. Committees established by the Board of Directors shall include:

(i) Representation by transplant coordinators, organ procurement organizations, and transplant hospitals, and at least one transplant candidate, transplant recipient, organ donor or family member; and

(ii) To the extent practicable, minority and gender representation reflecting the diversity of the population of transplant candidates, transplant recipients, organ donors and family members served by the OPTN.

(b) *Membership of the OPTN.* (1) The OPTN shall admit and retain as members the following:

(i) All organ procurement organizations;

(ii) Transplant hospitals participating in the Medicare or Medicaid programs; and

(iii) Other organizations, institutions, and individuals that have an interest in the fields of organ donation or transplantation.

(2) To apply for membership in the OPTN:

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(i) An OPO shall provide to the OPTN the name and address of the OPO, and the latest year of designation under section 1138(b) of the Social Security Act;

(ii) A transplant hospital shall provide to the OPTN the name and address of the hospital, a list of its transplant programs by type of organ; and

(iii) Any other organization, institution, or individual eligible under paragraph (c)(1)(iii) of this section shall demonstrate to the OPTN an interest in the fields of organ donation or transplantation.

(3) The OPTN shall accept or reject as members entities or individuals described in paragraph (c)(1)(iii) of this section within 90 days.

(4) Applicants rejected for membership in the OPTN may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(i) Deny the appeal; or

(ii) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

(c) *Corporate status of the OPTN.* (1) The OPTN shall be a private, not-for-profit entity.

(2) The requirements of this section do not apply to any parent, sponsoring, or affiliated organization of the OPTN, or to any activities of the contracting organization that are not integral to the operation of the OPTN. Such an organization is free to establish its own corporate procedures.

(3) No OPTN member is required to become a member of any organization that is a parent, sponsor, contractor, or affiliated organization of the OPTN, to comply with the by-laws of any such organization, or to assume any corporate duties or obligations of any such organization.

(d) *Effective date.* The organization designated by the Secretary as the OPTN shall have until June 30, 2000, or six months from its initial designation as the OPTN, whichever is later, to meet the requirements of this section, except that the Secretary may extend such period for good cause.

[63 FR 16332, Apr. 2, 1998, as amended at 63 FR 35847, July 1, 1998; 64 FR 56658, Oct. 20, 1999]

§ 121.4 OPTN policies: Secretarial review and appeals.

(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

(1) Policies for the equitable allocation of cadaveric organs in accordance with § 121.8;

(2) Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;

(3) Policies that reduce inequities resulting from socioeconomic status, including, but not limited to:

(i) Ensuring that payment of the registration fee is not a barrier to listing for patients who are unable to pay the fee;

(ii) Procedures for transplant hospitals to make reasonable efforts to obtain from all available sources, financial resources for patients unable to pay such that these patients have an opportunity to obtain a transplant and necessary follow-up care;

(iii) Recommendations to private and public payers and service providers on ways to improve coverage of organ transplantation and necessary follow-up care; and

(iv) Reform of allocation policies based on assessment of their cumulative effect on socioeconomic inequities;

(4) Policies regarding the training and experience of transplant surgeons and transplant physicians in designated transplant programs as required by § 121.9;

(5) Policies for nominating officers and members of the Board of Directors; and

(6) Policies on such other matters as the Secretary directs.

(b) The Board of Directors shall:

(1) Provide opportunity for the OPTN membership and other interested parties to comment on proposed policies and shall take into account the comments received in developing and

adopting policies for implementation by the OPTN; and

(2) Provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies it recommends to be enforceable under § 121.10 (including allocation policies). These policies will not be enforceable until approved by the Secretary. The Board of Directors shall also provide to the Secretary, at least 60 days prior to their proposed implementation, proposed policies on such other matters as the Secretary directs. The Secretary will refer significant proposed policies to the Advisory Committee on Organ Transplantation established under § 121.12, and publish them in the FEDERAL REGISTER for public comment. The Secretary also may seek the advice of the Advisory Committee on Organ Transplantation established under § 121.12 on other proposed policies, and publish them in the FEDERAL REGISTER for public comment. The Secretary will determine whether the proposed policies are consistent with the National Organ Transplant Act and this part, taking into account the views of the Advisory Committee and public comments. Based on this review, the Secretary may provide comments to the OPTN. If the Secretary concludes that a proposed policy is inconsistent with the National Organ Transplant Act or this part, the Secretary may direct the OPTN to revise the proposed policy consistent with the Secretary's direction. If the OPTN does not revise the proposed policy in a timely manner, or if the Secretary concludes that the proposed revision is inconsistent with the National Organ Transplant Act or this part, the Secretary may take such other action as the Secretary determines appropriate, but only after additional consultation with the Advisory Committee on the proposed action.

(c) The OPTN Board of Directors shall provide the membership and the Secretary with copies of its policies as they are adopted, and make them available to the public upon request. The Secretary will publish lists of OPTN policies in the FEDERAL REGISTER, indicating which ones are enforceable under § 121.10 or subject to potential sanctions of section 1138 of the

Social Security Act. The OPTN shall also continuously maintain OPTN policies for public access on the Internet, including current and proposed policies.

(d) Any interested individual or entity may submit to the Secretary in writing critical comments related to the manner in which the OPTN is carrying out its duties or Secretarial policies regarding the OPTN. Any such comments shall include a statement of the basis for the comments. The Secretary will seek, as appropriate, the comments of the OPTN on the issues raised in the comments related to OPTN policies or practices. Policies or practices that are the subject of critical comments remain in effect during the Secretary's review, unless the Secretary directs otherwise based on possible risk to the health of patients or to public safety. The Secretary will consider the comments in light of the National Organ Transplant Act and the regulations under this part and may consult with the Advisory Committee on Organ Transplantation established under § 121.12. After this review, the Secretary may:

- (1) Reject the comments;
- (2) Direct the OPTN to revise the policies or practices consistent with the Secretary's response to the comments; or
- (3) Take such other action as the Secretary determines appropriate.

(e) The OPTN shall implement policies and shall:

- (1) Provide information to OPTN members about these policies and the rationale for them; and
- (2) Update policies developed in accordance with this section to accommodate scientific and technological advances.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56658, Oct. 20, 1999]

§ 121.5 Listing requirements.

(a) A transplant hospital which is an OPTN member may list individuals, consistent with the OPTN's criteria under § 121.8(b)(1), only for a designated transplant program.

(b) Transplant hospitals shall assure that individuals are placed on the waiting list as soon as they are determined to be candidates for transplantation.

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The OPTN shall advise transplant hospitals of the information needed for such listing.

(c) An OPTN member shall pay a registration fee to the OPTN for each transplant candidate it places on the waiting list. The amount of such fee shall be calculated to cover (together with contract funds awarded by the Secretary) the reasonable costs of operating the OPTN and shall be determined by the OPTN with the approval of the Secretary. No less often than annually, and whether or not a change is proposed, the OPTN shall submit to the Secretary a statement of its proposed registration fee, together with such supporting information as the Secretary finds necessary to determine the reasonableness or adequacy of the fee schedule and projected revenues. This submission is due at least three months before the beginning of the OPTN's fiscal year. The Secretary will approve, modify, or disapprove the amount of the fee within a reasonable time of receiving the OPTN's submission.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56659, Oct. 20, 1999]

§ 121.6 Organ procurement.

The suitability of organs donated for transplantation shall be determined as follows:

(a) *Tests.* An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.

(b) *HIV.* The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus.

(c) *Acceptance criteria.* Transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56659, Oct. 20, 1999]

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§ 121.7 Identification of organ recipient.

(a) *List of potential transplant recipients.* (1) An OPTN member procuring an organ shall operate the OPTN computer match program within such time as the OPTN may prescribe to identify and rank potential recipients for each cadaveric organ procured.

(2) The rank order of potential recipients shall be determined for each cadaveric organ using the organ specific allocation criteria established in accordance with § 121.8.

(3) When a donor or donor organ does not meet a transplant program's donor acceptance criteria, as established under § 121.6(c), transplant candidates of that program shall not be ranked among potential recipients of that organ and shall not appear on a roster of potential recipients of that organ.

(b) *Offer of organ for potential recipients.* (1) Organs shall be offered for potential recipients in accordance with policies developed under § 121.8 and implemented under § 121.4.

(2) Organs may be offered only to potential recipients listed with transplant programs having designated transplant programs of the same type as the organ procured.

(3) An organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.

(4) A transplant program shall either accept or refuse the offered organ for the designated potential recipient within such time as the OPTN may prescribe. A transplant program shall document and provide to the OPO and to the OPTN the reasons for refusal and shall maintain this document for one year.

(c) *Transportation of organ to potential recipient—(1) Transportation.* The OPTN member that procures a donated organ shall arrange for transportation of the organ to the transplant hospital.

(2) *Documentation.* The OPTN member that is transporting an organ shall assure that it is accompanied by written documentation of activities conducted to determine the suitability of the organ donor and shall maintain this document for one year.

(3) *Packaging.* The OPTN member that is transporting an organ shall assure that it is packaged in a manner that is designed to maintain the viability of the organ.

(d) *Receipt of an organ.* Upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with the transplant. In the event that an organ is not transplanted into the potential recipient, the OPO which has a written agreement with the transplant hospital must offer the organ for another potential recipient in accordance with paragraph (b)(2) of this section.

(e) *Blood vessels considered part of an organ.* A blood vessel that is considered part of an organ under this part shall be subject to the allocation requirements and policies pertaining to the organ with which the blood vessel is procured until and unless the transplant center receiving the organ determines that the blood vessel is not needed for the transplantation of that organ.

(f) *Wastage.* Nothing in this section shall prohibit a transplant program from transplanting an organ into any medically suitable candidate if to do otherwise would result in the organ not being used for transplantation. The transplant program shall notify the OPTN and the OPO which made the organ offer of the circumstances justifying each such action within such time as the OPTN may prescribe.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56659, Oct. 20, 1999; 72 FR 10925, Mar. 12, 2007]

§ 121.8 Allocation of organs.

(a) *Policy development.* The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:

(1) Shall be based on sound medical judgment;

(2) Shall seek to achieve the best use of donated organs;

(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for

the potential recipient in accordance with § 121.7(b)(4)(d) and (e);

(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;

(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;

(6) Shall be reviewed periodically and revised as appropriate;

(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and

(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)–(5) of this section.

(b) *Allocation performance goals.* Allocation policies shall be designed to achieve equitable allocation of organs among patients consistent with paragraph (a) of this section through the following performance goals:

(1) Standardizing the criteria for determining suitable transplant candidates through the use of minimum criteria (expressed, to the extent possible, through objective and measurable medical criteria) for adding individuals to, and removing candidates from, organ transplant waiting lists;

(2) Setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria, for patients or categories of patients who are medically suitable candidates for transplantation to receive transplants. These rankings shall be ordered from most to least medically urgent (taking into account, in accordance with paragraph (a) of this section, and in particular in accordance with sound medical judgment, that life sustaining technology allows alternative approaches to setting priority ranking for patients). There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency;

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(3) Distributing organs over as broad a geographic area as feasible under paragraphs (a)(1)-(5) of this section, and in order of decreasing medical urgency; and

(4) Applying appropriate performance indicators to assess transplant program performance under paragraphs (c)(2)(i) and (c)(2)(ii) of this section and reducing the inter-transplant program variance to as small as can reasonably be achieved in any performance indicator under paragraph (c)(2)(iii) of this section as the Board determines appropriate, and under paragraph (c)(2)(iv) of this section. If the performance indicator "waiting time in status" is used for allocation purposes, the OPTN shall seek to reduce the inter-transplant program variance in this indicator, as well as in other selected performance indicators, to as small as can reasonably be achieved, unless to do so would result in transplanting less medically urgent patients or less medically urgent patients within a category of patients.

(c) *Allocation performance indicators.* (1) Each organ-specific allocation policy shall include performance indicators. These indicators must measure how well each policy is:

(i) Achieving the performance goals set out in paragraph (b) of this section; and

(ii) Giving patients, their families, their physicians, and others timely and accurate information to assess the performance of transplant programs.

(2) Performance indicators shall include:

(i) Baseline data on how closely the results of current allocation policies approach the performance goals established under paragraph (b) of this section;

(ii) With respect to any proposed change, the amount of projected improvement in approaching the performance goals established under paragraph (b) of this section;

(iii) Such other indicators as the Board may propose and the Secretary approves; and

(iv) Such other indicators as the Secretary may require.

(3) For each organ-specific allocation policy, the OPTN shall provide to the Secretary data to assist the Secretary

in assessing organ procurement and allocation, access to transplantation, the effect of allocation policies on programs performing different volumes of transplants, and the performance of OPOs and the OPTN contractor. Such data shall be required on performance by organ and status category, including program-specific data, OPO-specific data, data by program size, and data aggregated by organ procurement area, OPTN region, the Nation as a whole, and such other geographic areas as the Secretary may designate. Such data shall include the following measures of inter-transplant program variation: risk-adjusted total life-years pre-and post-transplant, risk-adjusted patient and graft survival rates following transplantation, risk-adjusted waiting time and risk-adjusted transplantation rates, as well as data regarding patients whose status or medical urgency was misclassified and patients who were inappropriately kept off a waiting list or retained on a waiting list. Such data shall cover such intervals of time, and be presented using confidence intervals or other measures of variance, as may be required to avoid spurious results or erroneous interpretation due to small numbers of patients covered.

(d) *Transition patient protections—(1) General.* When the OPTN revises organ allocation policies under this section, it shall consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies. The transition procedures shall be transmitted to the Secretary for review together with the revised allocation policies.

(2) *Special rule for initial revision of liver allocation policies.* When the OPTN transmits to the Secretary its initial revision of the liver allocation policies, as directed by paragraph (e)(1) of this section, it shall include transition procedures that, to the extent feasible, treat each individual on the waiting list and awaiting transplantation on October 20, 1999 no less favorably than he or she would have been treated had the revised liver allocation policies not

become effective. These transition procedures may be limited in duration or applied only to individuals with greater than average medical urgency if this would significantly improve administration of the list or if such limitations would be applied only after accommodating a substantial preponderance of those disadvantaged by the change in the policies.

(e) *Deadlines for initial reviews.* (1) The OPTN shall conduct an initial review of existing allocation policies and, except as provided in paragraph (e)(2) of this section, no later than November 16, 2000 shall transmit initial revised policies to meet the requirements of paragraphs (a) and (b) of this section, together with supporting documentation to the Secretary for review in accordance with § 121.4.

(2) No later than March 16, 2000 the OPTN shall transmit revised policies and supporting documentation for liver allocation to meet the requirements of paragraphs (a) and (b) of this section to the Secretary for review in accordance with § 121.4. The OPTN may transmit these materials without seeking further public comment under § 121.4(b).

(f) *Secretarial review of policies, performance indicators, and transition patient protections.* The OPTN's transmittal to the Secretary of proposed allocation policies and performance indicators shall include such supporting material, including the results of model-based computer simulations, as the Secretary may require to assess the likely effects of policy changes and as are necessary to demonstrate that the proposed policies comply with the performance indicators and transition procedures of paragraphs (c) and (d) of this section.

(g) *Variances.* The OPTN may develop, in accordance with § 121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of § 121.4.

(h) *Directed donation.* Nothing in this section shall prohibit the allocation of

an organ to a recipient named by those authorized to make the donation.

[64 FR 56659, Oct. 20, 1999, as amended at 64 FR 71626, Dec. 21, 1999]

§ 121.9 Designated transplant program requirements.

(a) To receive organs for transplantation, a transplant program in a hospital that is a member of the OPTN shall abide by these rules and shall:

(1) Be a transplant program approved by the Secretary for reimbursement under Medicare; or

(2) Be an organ transplant program which has adequate resources to provide transplant services to its patients and agrees promptly to notify the OPTN and patients awaiting transplants if it becomes inactive and which:

(i) Has letters of agreement or contracts with an OPO;

(ii) Has on site a transplant surgeon qualified in accordance with policies developed under § 121.4;

(iii) Has on site a transplant physician qualified in accordance with policies developed under § 121.4;

(iv) Has available operating and recovery room resources, intensive care resources and surgical beds and transplant program personnel;

(v) Shows evidence of collaborative involvement with experts in the fields of radiology, infectious disease, pathology, immunology, anesthesiology, physical therapy and rehabilitation medicine, histocompatibility, and immunogenetics and, as appropriate, hepatology, pediatrics, nephrology with dialysis capability, and pulmonary medicine with respiratory therapy support;

(vi) Has immediate access to microbiology, clinical chemistry, histocompatibility testing, radiology, and blood banking services, as well as the capacity to monitor treatment with immunosuppressive drugs; and

(vii) Makes available psychiatric and social support services for transplant candidates, transplant recipients, and their families; or

(3) Be a transplant program in a Department of Veterans Affairs, Department of Defense, or other Federal hospital.

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(b) To apply to be a designated transplant program, transplant programs shall provide to the OPTN such documents as the OPTN may require which show that they meet the requirements of § 121.9(a) (1), (2), or (3).

(c) The OPTN shall, within 90 days, accept or reject applications to be a designated transplant program.

(d) Applicants rejected for designation may appeal to the Secretary. Appeals shall be submitted in writing within 30 days of rejection of the application. The Secretary may:

(1) Deny the appeal; or

(2) Direct the OPTN to take action consistent with the Secretary's response to the appeal.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56660, Oct. 20, 1999]

§ 121.10 Reviews, evaluation, and enforcement.

(a) *Review and evaluation by the Secretary.* The Secretary or her/his designee may perform any reviews and evaluations of member OPOs and transplant programs which the Secretary deems necessary to carry out her/his responsibilities under the Public Health Service Act and the Social Security Act.

(b) *Review and evaluation by the OPTN.* (1) The OPTN shall design appropriate plans and procedures, including survey instruments, a peer review process, and data systems, for purposes of:

(i) Reviewing applications submitted under § 121.3(c) for membership in the OPTN;

(ii) Reviewing applications submitted under § 121.9(b) to be a designated transplant program; and

(iii) Conducting ongoing and periodic reviews and evaluations of each member OPO and transplant hospital for compliance with these rules and OPTN policies.

(2) Upon the approval of the Secretary, the OPTN shall furnish review plans and procedures, including survey instruments and a description of data systems, to each member OPO and transplant hospital. The OPTN shall furnish any revisions of these documents to member OPOs and hospitals, after approval by the Secretary, prior to their implementation.

(3) At the request of the Secretary, the OPTN shall conduct special reviews of OPOs and transplant programs, where the Secretary has reason to believe that such entities may not be in compliance with these rules or OPTN policies or may be acting in a manner which poses a risk to the health of patients or to public safety. The OPTN shall conduct these reviews in accordance with such schedules as the Secretary specifies and shall make periodic reports to the Secretary of progress on such reviews and on other reviews conducted under the requirements of this paragraph.

(4) The OPTN shall notify the Secretary in a manner prescribed by the Secretary within 3 days of all committee and Board of Directors meetings in which transplant hospital and OPO compliance with these regulations or OPTN policies is considered.

(c) *Enforcement of OPTN rules—(1) OPTN recommendations.* The Board of Directors shall advise the Secretary of the results of any reviews and evaluations conducted under paragraph (b)(1)(iii) or paragraph (b)(3) of this section which, in the opinion of the Board, indicate noncompliance with these rules or OPTN policies, or indicate a risk to the health of patients or to the public safety, and shall provide any recommendations for appropriate action by the Secretary. Appropriate action may include removal of designation as a transplant program under § 121.9, termination of a transplant hospital's participation in Medicare or Medicaid, termination of a transplant hospital's reimbursement under Medicare and Medicaid, termination of an OPO's reimbursement under Medicare and Medicaid, if the noncompliance is with a policy designated by the Secretary as covered by section 1138 of the Social Security Act, or such other compliance or enforcement measures contained in policies developed under § 121.4.

(2) *Secretary's action on recommendations.* Upon the Secretary's review of the Board of Directors' recommendations, the Secretary may:

(i) Request further information from the Board of Directors or the alleged violator, or both;

- (ii) Decline to accept the recommendation;
- (iii) Accept the recommendation, and notify the alleged violator of the Secretary's decision; or
- (iv) Take such other action as the Secretary deems necessary.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999]

§ 121.11 Record maintenance and reporting requirements.

- (a) *Record maintenance.* Records shall be maintained and made available subject to OPTN policies and applicable limitations based on personal privacy as follows:
 - (1) The OPTN and the Scientific Registry, as appropriate, shall:
 - (i) Maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors, including a computerized list of individuals waiting for transplants;
 - (ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients;
 - (iii) Operate, maintain, receive, publish, and transmit such records and information electronically, to the extent feasible, except when hard copy is requested; and
 - (iv) In making information available, provide manuals, forms, flow charts, operating instructions, or other explanatory materials as necessary to understand, interpret, and use the information accurately and efficiently.
 - (2) *Organ procurement organizations and transplant programs*—(i) *Maintenance of records.* All OPOs and transplant programs shall maintain such records pertaining to each potential donor identified, each organ retrieved, each recipient transplanted and such other transplantation-related matters as the Secretary deems necessary to carry out her/his responsibilities under the Act. The OPO or transplant program shall maintain these records for seven years.
 - (ii) *Access to facilities and records.* OPOs and transplant hospitals shall permit the Secretary and the Comptroller General, or their designees, to inspect facilities and records pertaining to any aspect of services per-
- formed related to organ donation and transplantation.

- (b) *Reporting requirements.* (1) The OPTN and the Scientific Registry, as appropriate, shall:
 - (i) In addition to special reports which the Secretary may require, submit to the Secretary a report not less than once every fiscal year on a schedule prescribed by the Secretary. The report shall include the following information in a form prescribed by the Secretary:
 - (A) Information that the Secretary prescribes as necessary to assess the effectiveness of the Nation's organ donation, procurement and transplantation system;
 - (B) Information that the Secretary deems necessary for the report to Congress required by Section 376 of the Act; and,
 - (C) Any other information that the Secretary prescribes.
 - (ii) Provide to the Scientific Registry data on transplant candidates and recipients, and other information that the Secretary deems appropriate. The information shall be provided in the form and on the schedule prescribed by the Secretary;
 - (iii) Provide to the Secretary any data that the Secretary requests;
 - (iv) Make available to the public timely and accurate program-specific information on the performance of transplant programs. This shall include free dissemination over the Internet, and shall be presented, explained, and organized as necessary to understand, interpret, and use the information accurately and efficiently. These data shall be updated no less frequently than every six months (or such longer period as the Secretary determines would provide more useful information to patients, their families, and their physicians), and shall include risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing for such intervals as the Secretary shall prescribe. These data shall include confidence intervals or other measures that provide information on the extent to which chance

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may influence transplant program-specific results. Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

(v) Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary. The OPTN or the Scientific Registry may impose reasonable charges for the separable costs of responding to such requests. Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed. All requests shall be processed expeditiously, with data normally made available within 30 days from the date of request;

(vi) Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes. The OPTN or Scientific Registry may impose charges for the separable costs of responding to such requests. An estimate of such charges shall be provided to the requester before processing the request. All requests should be processed expeditiously, with data normally made available within 30 days from the date of request; and

(vii) Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

(2) An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding

transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.

(c) *Public access to data.* The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual transplant programs, and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999]

§ 121.12 Advisory Committee on Organ Transplantation.

The Secretary will establish, consistent with the Federal Advisory Committee Act, the Advisory Committee on Organ Transplantation. The Secretary may seek the comments of the Advisory Committee on proposed OPTN policies and such other matters as the Secretary determines.

[64 FR 56661, Oct. 20, 1999]

§ 121.13 Definition of Human Organ Under section 301 of the National Organ Transplant Act, as amended.

“Human organ,” as covered by section 301 of the National Organ Transplant Act, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and intestine,

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including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.

[72 FR 10619, Mar. 9, 2007]

PART 124—MEDICAL FACILITY CONSTRUCTION AND MODERNIZATION**Subpart A—Project Grants for Public Medical Facility Construction and Modernization**

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- 124.1 Applicability.
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- 124.601 Applicability.
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APPENDIX TO SUBPART G—INTERIM PROCEDURES AND CRITERIA FOR REVIEW BY HEALTH SYSTEMS AGENCIES OF APPLICATIONS UNDER SECTION 1625 OF THE PUBLIC HEALTH SERVICE ACT

Subpart H—Recovery of Grant Funds

- 124.701 Applicability.
- 124.702 Definitions.
- 124.703 Federal right of recovery.
- 124.704 Notification of sale, transfer, or change of use.
- 124.705 Amount of recovery.
- 124.706 Calculation of interest.
- 124.707 Waiver of recovery where facility is sold or transferred to a proprietary entity.
- 124.708 Waiver of recovery—good cause for other use of facility.
- 124.709 Withdrawal of waiver.

AUTHORITY: Secs. 215, 1602, 1625, Public Health Service Act (42 U.S.C. 216, 300o-1, 300r), unless otherwise noted.

SOURCE: 42 FR 62270, Dec. 9, 1977, unless otherwise noted.

Subpart A—Project Grants for Public Medical Facility Construction and Modernization**§ 124.1 Applicability.**

The regulations of this subpart are applicable to grants under section 1625 of the Public Health Service Act for construction and modernization projects designed to:

(a) Eliminate or prevent imminent safety hazards as defined by Federal, State or local fire, building, or life safety codes or regulations, or

(b) Avoid noncompliance with State or voluntary licensure or accreditation standards.

§ 124.2 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Construction* means construction of new buildings and initial equipment of such buildings and, in any case in

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which it will help to provide a service not previously provided in the community, equipment of any buildings. It includes architect's fees, but excludes the cost of off-site improvements and, except with respect to public health centers, the cost of the acquisition of land.

(c) *Cost* means the amount found by the Secretary to be necessary for construction or modernization under a project, except that such term does not include any amount found by the Secretary to be attributable to expansion of the bed capacity of any facility.

(d) *Equipment* means those items which are necessary for the functioning of the facility but does not include items of current operating expense such as food, fuel, pharmaceuticals, dressings, paper, printed forms, and housekeeping supplies.

(e) *Facility for long-term care* means a facility (including a skilled nursing care or intermediate care facility), providing inpatient care for convalescent or chronic disease patients who require skilled nursing or intermediate care and related medical services:

(1) Which is a hospital (other than a hospital primarily for the care and treatment of mentally ill or tuberculosis patients) or is operated in connection with a hospital, or

(2) In which such care and medical services are prescribed by, or are performed under the general direction of, persons licensed to practice medicine or surgery in the State.

(f) *Health systems agency* means an agency which has been conditionally or fully designated pursuant to section 1515 of the Act and 42 CFR part 122.

(g) *Hospital* includes general, tuberculosis, and other types of hospitals, and related facilities such as laboratories, outpatient departments, nurses' home facilities, extended care facilities, facilities related to programs for home health services, self-care units, and central service facilities, operated in connection with hospitals, and education or training facilities for health professional personnel operated as an integral part of a hospital, but does not include any facility furnishing primarily domiciliary care.

(h) *Major repair* means those repairs to an existing building, excluding routine maintenance, which restore the

building to a sound state, the cost of which is at least 10 percent of plant value or \$200,000, whichever is greater. *Plant value* means the historic book value of the building at the time of application for assistance under this subpart.

(i) *Medical facility* means a hospital, public health center, outpatient medical facility, rehabilitation facility, or a facility for long-term care.

(j) *Modernization* means the alteration, expansion (excluding expansion which increases bed capacity), major repair, remodeling, replacement, and renovation of existing buildings (including initial equipment thereof), and the replacement of obsolete equipment of existing buildings, including energy conservation projects.

(k) *Outpatient medical facility* means a facility, located in or apart from a hospital, for the diagnosis or diagnosis and treatment of ambulatory patients (including ambulatory inpatients):

(1) Which is operated in connection with a hospital, or

(2) In which patient care of a specialized nature (such as in an eye clinic, dental clinic, or ambulatory surgical center) is provided under the professional supervision of persons licensed to practice medicine or surgery in the State, or in the case of dental diagnosis or treatment, under the professional supervision of persons licensed to practice dentistry in the State, or

(3) Which offers to patients not requiring hospitalization the services of licensed physicians in various medical specialties, and which provides to its patients a reasonably full range of diagnostic and treatment services.

(l) *Public health center* means a publicly owned facility for the provision of public health services, including related facilities such as laboratories, clinics, and administrative offices operated in connection with such a facility.

(m) *Quasi-public corporation* means a private, nonprofit corporation which has been formally given one or more governmental powers by a general-purpose unit of government to enable it to carry out its work.

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(n) *Rehabilitation facility* means a facility which is operated for the primary purpose of assisting in the rehabilitation of disabled persons through an integrated program of medical evaluation and services, and psychological, social, or vocational evaluation and services, under competent professional supervision, and in the case of which the major portion of the required evaluation and services is furnished within the facility; and either the facility is operated in connection with a hospital, or all medical and related health services are prescribed by, or are under the general direction of persons licensed to practice medicine or surgery in the State.

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

(p) *State* means any one of the several States, the Commonwealth of Puerto Rico, Guam, American Samoa, the Trust Territory of the Pacific Islands, the Virgin Islands, and the District of Columbia.

(q) *State health planning and development agency or State Agency* means the agency of a State government which has been conditionally or fully designated under section 1521 of the Act and 42 CFR part 123.

(r) *Title* means a fee simple, or such other estate or interest in the project site (including a leasehold on which the rental does not exceed 4 percent of the value of the land) as the Secretary finds sufficient to assure undisturbed use and possession for the purpose of construction or modernization and operation of the project for a period of not less than twenty years.

(s) *Urban or rural poverty area* means a census tract, census county division, or minor civil division, as applicable, in which the percentage of the residents with incomes below the poverty level, as defined by the Secretary of Commerce is not less than the percentage derived in accordance with the following sentence. This percentage shall be derived so that the percentage of the total population of the United States residing in all such areas is equal to the percentage of the total population

of the United States with incomes below such poverty level, plus five percent.

§ 124.3 Eligibility.

(a) *Eligible applicants.* A grant under section 1625 may only be made to a State or political subdivision of a State, including any city, town, county, borough, hospital district authority, or public or quasi-public corporation for a project described in paragraph (b) of this section for a medical facility owned, operated, or owned and operated by the State or political subdivision.

(b) *Eligible project.* A grant under section 1625 may be made only for a construction and/or modernization project designed to:

(1) Eliminate or prevent safety hazards which under Federal, State, and/or local fire, building or life safety codes or regulations, will, in the judgment of the Secretary result in one or more of the following:

(i) Loss of licensure for the facility.

(ii) Closing of all or a substantial part of the facility,

(iii) Loss of eligibility for reimbursement under title XVIII or title XIX of the Social Security Act; or

(2) Avoid noncompliance with State licensure or voluntary accreditation standards where noncompliance will, in the judgment of the Secretary, result in one or both of the following:

(i) Loss of licensure for the facility.

(ii) Loss of accreditation resulting in loss of eligibility for reimbursement under title XVIII or title XIX of the Social Security Act.

§ 124.4 Application.

An application for a grant under this subpart must be submitted directly to the Secretary at such time and in such form and manner as the Secretary may prescribe. The application must be executed by an individual authorized to act for the applicant and assume on behalf of the applicant the obligations imposed by the Act, this subpart, and the terms and conditions of the grant. The application must contain the following:

(a) A description of the site of the project.

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(b) A full description, with all appropriate documentation, of:

(1) The imminent safety hazards, licensure and/or accreditation problems of the facility;

(2) The type and amount of assistance sought under this subpart;

(3) The construction of modernization project for which funds are sought, describing how it will remedy the problems described pursuant to paragraph (b)(1) of this section, with a complete schedule for the proposed construction or modernization; and

(4) How failure to remedy the problems described pursuant to paragraph (b) (1) of this section will affect the population served by the facility.

(c) In the case of a modernization project for continuation of existing health services, a finding by the State Agency of the continued need for such services. In the case of a construction or modernization project for new health services, a finding by the State Agency of the need for such services. The finding of need shall be based on the following criteria:

(1) In a State which has a program approved by the Secretary under section 1523(a)(4)(B) of the Act, a State certificate of need program, or a program under section 1122 of the Social Security Act, the State Agency shall use the criteria used in conducting reviews under such program. In a State which has more than one such program, the State Agency shall use the criteria of one of the programs and notify the Secretary of the program criteria used.

(2) In a State which does not have a program approved by the Secretary under section 1523(a)(4)(B) of the Act, a State certificate of need program or a program under section 1122 of the Social Security Act, the State Agency shall base its finding of need on the following criteria:

(i) Whether the proposed project is needed or projected as necessary to meet the needs in the community in terms of health services required; *Provided*, That projects for highly specialized services (such as open-heart surgery, renal transplantation, or radiation therapy) which will draw from patient populations outside the com-

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munity in which the project is situated will receive appropriate consideration;

(ii) Whether the proposed project can be adequately staffed and operated when completed;

(iii) Whether the proposed capital expenditure is economically feasible and can be accommodated in the patient charge structure of the health facility without unreasonable increases; and

(iv) Whether the project will foster cost containment or improved quality of care through improved efficiency and productivity, including promotion of cost-effective factors such as ambulatory care, preventive health care services, home health care, and design and construction economies, or through increased competition between different health services delivery systems.

(d) [Reserved]

(e) An assurance that adequate financial support will be available for completion of the project, supported by a detailed project budget satisfactory to the Secretary which includes all existing and anticipated sources of funds for the project.

(f) An assurance that adequate financial support will be available for maintenance and operation of the project when completed, supported by budgets and detailed expenditure and revenue information satisfactory to the Secretary for both the facility and the applicant for the past three fiscal years and budget and projections of expenditures and revenue for the future three fiscal years. Where a certificate of need or a favorable finding under section 1122 of the Social Security Act is required in order for the project to operate and/or receive reimbursement from governmental programs for health services provided, assurance from the applicant satisfactory to the Secretary that the applicant will submit, consistent with the provisions of § 124.5(d), any such required certificates of need and/or section 1122 finding.

(g) An assurance that the applicant would not be able to complete the project without the grant applied for, supported by a description of all efforts to obtain funds needed to complete the project and the results of such efforts.

(h) An assurance that all times after the application is approved 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 applicant shall comply with the standards and procedures of 42 CFR 53.111, except as the Secretary may prescribe pursuant to section 1602(6) of the Act. The functions of the State Agency designated under section 604 of the Act under 42 CFR 53.111 will be performed by the Secretary, except to the extent they are otherwise assigned.

(i) An assurance that at all times after the application is approved the facility or portion thereof to be constructed or modernized will be made available to all persons residing or employed in the area served by the facility. The applicant shall comply with the standards and procedures of 42 CFR 53.113, except as the Secretary may prescribe pursuant to section 1602(6) of the Act. The functions of the State Agency designated under section 604 of the Act under 42 CFR 53.113 will be performed by the Secretary, except to the extent they are otherwise assigned.

(j) An assurance that title to the project site is or will be vested in one or more of the entities filing the application or in a public or other nonprofit entity which is to operate the facility on completion of the project, with such documentation as the Secretary may require.

(k) In the case of an application for construction or modernization of an outpatient medical facility, an assurance, supported by a written transfer agreement (or written documentation that such agreement will be obtained) with identified hospitals, that the services of a general hospital will be available to patients at such facility who are in need of hospital care.

(l) Evidence that: (1) The appropriate health systems agency has been given the opportunity to review the application in accordance with section 1513(e) of the Act and the requirements of the appendix to this subpart, with the result of any such review.

(2) The application has been reviewed in accordance with the applicable requirements of OMB Circular A-95.

(m) An analysis satisfactory to the Secretary and such other information and materials as the Secretary may re-

quire concerning the environmental impact of the proposed construction or modernization project.

(n) An assessment satisfactory to the Secretary of the project site in light of the considerations set forth in Executive Order 11296 (31 FR 10663, August 10, 1966) concerning the evaluation of flood hazards in locating Federally supported facilities.

(o) In the case of a project which involves the displacement of persons or businesses, an assurance that the applicant will comply with the applicable provisions of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (42 U.S.C. 4601 *et seq.*).

(p)(1) An assurance that all laborers and mechanics employed by contractors or subcontractors in the performance of work on a project will be paid wages at rates not less than those prevailing on similar construction in the locality as determined by the Secretary of Labor in accordance with the Act of March 3, 1931 (40 U.S.C. 276a-276a-5, known as the Davis-Bacon Act); and

(2) An assurance that the following conditions and provisions will be included in all construction contracts:

(i) The provisions of "DHHS Requirements for Federally Assisted Construction Contracts Regarding Labor Standards and Equal Employment Opportunity," Form DHHS 514 (rev. July 1976) (issued by the Office of Grants and Procurement Management, U.S. Department of Health and Human Services) pertaining to the Davis-Bacon Act, the Contract Work Hours Standards Act, and the Copeland Act (Anti-Kickback) regulations except in the case of contracts in the amount of \$2,000 or less; and pertaining to Executive Order 11246, September 24, 1965 (30 FR 12319), relating to nondiscrimination in construction contract employment except in the case of contracts in the amount of \$10,000 or less, and

(ii) Representatives of the Secretary will have access at all reasonable times to work wherever it is in preparation or progress, and the contractor shall provide proper facilities for such access and inspection.

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(q) Such other information as the Secretary may require.

[42 FR 62270, Dec. 9, 1977, as amended at 49 FR 33021, Aug. 20, 1984]

§ 124.5 Grant evaluation and award.

(a)(1) Within the limits of funds available for such purpose, the Secretary may award grants under this subpart for project costs to applicants with approvable applications therefor which will, in his judgment, best promote the purposes of section 1625 of the Act, taking into consideration:

(i) The severity and seriousness of the safety hazard, licensure or accreditation problem or problems.

(ii) The relative need of the population to be served for the services to be provided, including the availability of alternatives for meeting the need.

(iii) The financial need of the applicant.

(iv) The extent to which the facility will serve persons below the poverty level, as determined by the Secretary of Commerce.

(v) The extent to which the project will foster cost containment or improve the quality of care through enhanced efficiency and productivity.

(2) Priority for funding shall be based on the extent to which services will be made available relative to the cost of the project.

(b) The amount of any grant under this subpart may not exceed 75 percent of the cost of the project for which the grant is made unless the project is located in an area determined by the Secretary to be an urban or rural poverty area, in which case the grant may, as determined by the Secretary, cover up to 100 percent of such costs.

(c) If an applicant has not entered into a legally enforceable fixed price contract for the project for which funds are awarded under this subpart within 180 days of the date of the grant award, the grant award will automatically become null and void.

(d) Where a grant has been awarded to an applicant under this subpart on the condition that any applicable certificates of need and section 1122 finding required under § 124.4(f) will be provided, if such certificates and finding have not been received by the Secretary within 180 days of the grant

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award, the grant award will automatically become null and void.

§ 124.6 Grant payments.

Grant payments shall be made to the applicant in accordance with the requirements of subpart K of 45 CFR part 74.

§ 124.7 Use of grant funds.

Any funds granted pursuant to this subpart, as well as funds assured by the applicant for the project, shall be expended solely for carrying out the approved project in accordance with section 1625 of the Act, the regulations of this subpart, the terms and conditions of the grant award, and the applicable cost principles prescribed by subpart Q of 45 CFR part 74.

§ 124.8 Grantee accountability.

(a) *Records requirements.* (1) Applicants who have received Federal assistance under this subpart shall maintain, in accounting records which are separate from the records of all other funds, records which fully disclose the following:

(i) The amount of all payments received from the Secretary under this subpart,

(ii) Amounts and sources of all funds, in addition to funds received under this subpart, applied to the construction or modernization project funded under this subpart,

(iii) Disposition of all funds for the construction or modernization project funded under this subpart,

(iv) Total cost of the project approved under this subpart, and

(2) Upon request, applicants shall make such records, books, papers, or other documents available to the Secretary and the Comptroller General of the United States or any of their duly authorized representatives which, in their opinion, may be related or pertinent to the grant under this subpart.

(b) *Annual financial statement.* An applicant who receives grant assistance under this subpart shall, not later than 120 days after the end of its fiscal year, unless a longer period is approved by the Secretary for good cause shown, file an annual financial statement which meets the requirements of section 1634 of the Act.

§ 124.9 Nondiscrimination.

(a) 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 that 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 is applicable to grants made under this subpart, has been issued by the Secretary with the approval of the President (45 CFR part 80).

(b) Attention is called to the requirements of section 504 of the Rehabilitation Act of 1973, as amended, which provides that no otherwise qualified handicapped individual in the United States shall, solely by reason of the handicap, 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 section 504 has been issued (45 CFR part 84 (42 FR 22676, May 4, 1977)).

(c) 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 must be made available without discrimination on account of creed and the applicant may not discriminate against any qualified person on account of creed with respect to the privilege of professional practice in the facility.

(d) Attention is also called to the requirements of title IX of the Education amendments of 1972 and in particular to section 901 of such Act (20 U.S.C. 1681) which provides that no person in the United States shall, on the basis of sex be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any education program or activity receiving Federal financial assistance (45 CFR part 86).

(e) Each construction contract is subject to the condition that the applicant shall comply with the requirements of section 321 of the Comprehensive Alco-

hol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970, as amended, which provides that alcohol abusers and alcoholics who are suffering from medical conditions shall not be discriminated against in admission or treatment, solely because of their alcohol abuse or alcoholism by any private or public general hospital that receives support in any form from any federally funded program.

(f) Each construction contract is subject to the condition that the applicant shall comply with the requirements of section 407 of the Drug Abuse Office and Treatment Act of 1972, as amended, which provides that drug abusers who are suffering from medical conditions shall not be discriminated against because of their drug abuse or drug dependence, by any private or public general hospital that receives support in any form from any federally funded program.

§ 124.10 Additional conditions.

The Secretary may impose additional conditions prior to or at the time of any grant award when in the Secretary's judgment such conditions are necessary to assure or protect advancement of the project in accordance with the purposes of the Act and the regulations of this subpart or the conservation of grant funds.

§ 124.11 Applicability of 45 CFR part 74.

The provisions of 45 CFR part 74, establishing uniform administrative requirements and cost principles, shall apply to all grants under this subpart to State and local governments as those terms are defined in subpart A of that part 74, except to the extent inconsistent with this subpart. The relevant provisions of the following subparts of part 74 shall also apply to grants to all other grantee organizations under this subpart.

45 CFR PART 74

Subpart:

- A General.
- B Cash depositories.
- C Bonding and insurance.
- F Grant-related income.
- G Matching and cost sharing.
- L Budget revision procedures.

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- M Grant closeout, suspension, and termination.
- O Property.
- P Procurement standards.
- Q Cost principles.

Subparts B-E [Reserved]

Subpart F—Reasonable Volume of Uncompensated Services to Persons Unable To Pay

AUTHORITY: 42 U.S.C. 216; 42 U.S.C. 300s(3).

SOURCE: 52 FR 46031, Dec. 3, 1987, unless otherwise noted.

§ 124.501 Applicability.

(a) The provisions of this subpart apply to any recipient of Federal assistance under title VI or XVI of the Public Health Service Act that gave an assurance that it would make available, in the facility or portion of the facility constructed, modernized or converted with that assistance, a reasonable volume of services to persons unable to pay for the services.

(b) The provisions of this subpart apply to facilities for the following periods:

(1) *Facilities assisted under title VI.* Except as otherwise herein provided, a facility assisted under title VI of the Act shall provide uncompensated services at the annual compliance level required by § 124.503(a) for:

(i) Twenty years after the completion of construction, in the case of a facility for which the Secretary provided grant assistance under section 606 of the Act; or

(ii) The period from completion of construction until the amount of a direct loan under sections 610 and 623 of the Act, or the amount of a loan with respect to which the Secretary provided a guarantee and interest subsidy under section 623 of the Act, is repaid, in the case of a facility for which such a loan was made.

(iii) “Completion of construction” means:

(A) The date on which the Secretary determines the facility was opened for service;

(B) If the opening date is not available, it means the date on which the Secretary approved the final part of

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the facility's application for assistance under title VI of the Act;

(C) If the date of final approval is not available, it means whatever date the Secretary determines most reasonably approximates the date of final approval.

(2) *Facilities assisted under title XVI.* The provisions of this subpart apply to a facility assisted under title XVI of the Act at all times following the Secretary's approval of the facility's application for assistance under title XVI, except that if the facility does not at the time of that approval provide health services, the assurance applies at all times following the facility's initial provision of health services to patients, as determined by the Secretary.

§ 124.502 Definitions.

As used in this subpart—

(a) *Act* means the Public Health Service Act, as amended.

(b) *Allowable credit* for services provided to a specific patient means the lesser of the facility's usual charge for those services, or the usual charge multiplied by the percentage which the total allowable cost as reported by the facility in the facility's preceding fiscal year under title XVIII of the Social Security Act (42 U.S.C. 1395, *et seq.*) and the implementing regulations (42 CFR part 413) bears to the facility's total patient revenues for the year.

(c) *Applicant* means a person who requests uncompensated services or on whose behalf uncompensated services are requested.

(d) *CPI* means the National Consumer Price Index for medical care.

(e) *Facility* means an entity that received assistance under title VI or XVI of the Act and provided an assurance that it would provide a reasonable volume of services to persons unable to pay for the services.

(f) *Federal assistance* means assistance received by the facility under title VI or title XVI of the Act and any assistance supplementary to that title VI or title XVI assistance received by the facility under any of the following acts: the District of Columbia Medical Facilities Construction Act of 1968, 82 Stat. 631 (Pub. L. 90-457); the Public Works Acceleration Act of 1962 (42 U.S.C. 2641, *et seq.*); the Public Works

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and Economic Development Act of 1965 (42 U.S.C. 3121, *et seq.*); the Appalachian Regional Development Act of 1965, as amended (40 U.S.C. App.); the Local Public Works Capital Development and Investment Act of 1976 (Pub. L. 94-369). In the case of a loan guaranteed by the Secretary with an interest subsidy, the amount of Federal assistance under title VI or title XVI for a fiscal year is the total amount of the interest subsidy that the Secretary will have paid by the close of that fiscal year, as well as any other payments which the Secretary has made as of the beginning of the fiscal year on behalf of the facility in connection with the loan guarantee or the direct loan which has been sold.

(g) *Fiscal year* means the facility's fiscal year.

(h) *Nursing home* means a facility which received Federal assistance for and operates as a *facility for long-term care* as defined at, as applicable, section 645(h) or section 1624(6) of the Act.

(i) *Operating costs* for any fiscal year means the total operating expenses of a facility as set forth in an audited financial statement, minus the amount of reimbursement, if any, received (or if not received, claimed) in that year under titles XVIII and XIX of the Social Security Act.

(j) *Persons unable to pay* means persons who meet the eligibility criteria set out in § 124.505.

(k) *Request for uncompensated services* means any indication by or on behalf of an individual seeking services of the facility of the individual's inability to pay for services. A request for uncompensated services may be made at any time, including following institution of a collection action against the individual.

(l) *Secretary* means the Secretary of Health and Human Services or [his or her] delegatee.

(m) *Uncompensated services* means:

(1) For facilities other than those certified under § 124.513, § 124.514, § 124.515, or § 124.516, health services that are made available to persons unable to pay for them without charge or at a charge which is less than the allowable credit for those services. The amount of uncompensated services provided in a fiscal year is the total allowable credit for services less the amount

charged for the services following an eligibility determination. Excluded are services provided more than 96 hours following notification to the facility by a quality improvement organization that it disapproved the services under section 1155(a)(1) or section 1154(a)(1) of the Social Security Act.

(2) For facilities certified under § 124.513, § 124.514, § 124.515, or § 124.516, services as defined in paragraph (m)(1) of this section and services that are made available to persons unable to pay for them under programs described by the documentation provided under § 124.513(c)(2), § 124.514(c)(2), or § 124.516(c)(2), as applicable, or pursuant to the terms of the applicable grant or agreement as provided in § 124.515. Except as provided in § 124.516, excluded are services reimbursed by Medicare, Medicaid, or other third party programs, including services for which reimbursement was provided as payment in full, and services provided more than 96 hours following notification to the facility by a quality improvement organization that it disapproved the services under section 1155(a)(1) or section 1154(a)(1) of the Social Security Act.

[52 FR 46031, Dec. 3, 1987, as amended at 59 FR 44639, Aug. 30, 1994]

§ 124.503 Compliance level.

(a) *Annual compliance level.* Subject to the provisions of this subpart, a facility is in compliance with its assurance to provide a reasonable volume of services to persons unable to pay if it provides for the fiscal year uncompensated services at a level not less than the lesser of—

(1) Three percent of its operating costs for the most recent fiscal year for which an audited financial statement is available;

(2) Ten percent of all Federal assistance provided to or on behalf of the facility, adjusted by a percentage equal to the percentage change in the CPI between the year in which the facility received assistance or 1979, whichever is later, and the most recent year for which a published index is available.

(b) *Deficits.* If in any fiscal year a facility fails to meet its annual compliance level, it shall provide uncompensated services in an amount sufficient to make up that deficit in subsequent

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years, and its period of obligation shall be extended until the deficit is made up.

(1) *Types of deficits.* For purposes of determining the timing and amount of any deficit make-up, there are two types of deficits:

(i) *Justifiable deficits.* A justifiable deficit is one in which the facility did not meet its annual compliance level due to either financial inability (as determined under § 124.511(c)) or, although otherwise in compliance with this subpart, a lack of eligible applicants for uncompensated services during the fiscal year.

(ii) *Noncompliance deficits.* A noncompliance deficit is one in which the facility failed to meet its annual compliance level due to noncompliance with this subpart.

(2) *Timing of deficit make-up*—(i) *Justifiable deficits.* (A) A facility assisted under title VI of the Act may make up a justifiable deficit at any time during its period of obligation or in the year (or years, if necessary) immediately following its period of obligation.

(B) A facility assisted under title XVI of the Act is not required to make up a justifiable deficit.

(ii) *Noncompliance deficits.* (A) A facility must begin to make up a noncompliance deficit in the fiscal year following the finding of noncompliance by the Secretary.

(B) A facility which claimed financial inability under § 124.509(a)(2)(iii) and is found by the Secretary, pursuant to § 124.511(c), to have been financially able to provide uncompensated services in the year in which the deficit was incurred shall begin to make up the deficit beginning in the fiscal year following the Secretary's finding.

(C) A facility required to make up a noncompliance deficit but which is determined by the Secretary, pursuant to § 124.511(c), to be financially unable to do so in the year following the Secretary's finding of noncompliance shall make up the deficit in accordance with a schedule set by the Secretary.

(3) *Deficit make-up amount.* (i) The amount of a deficit in any fiscal year is the difference between the facility's annual compliance level for that year and the amount of uncompensated services provided in that year.

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(ii) The amount of a justifiable deficit must be adjusted by a percentage equal to the percentage change in the CPI between the CPI available in the fiscal year in which the deficit was incurred and the CPI available in the fiscal year in which it was made up.

(iii) An amount equal to the result of dividing the amount of any noncompliance deficit for a fiscal year by the number of years of obligation remaining and adjusting it by a percentage equal to the percentage change in the CPI between the CPI available in the fiscal year in which the deficit was incurred and the CPI available in the fiscal year in which it was made up shall be added to a facility's annual compliance level for each fiscal year following the fiscal year of the finding of noncompliance.

(4) *Affirmative action plan for precluding future deficits.* Except where a facility reports to the Secretary in accordance with § 124.509(a)(2)(iii) that it was financially unable to provide uncompensated services at the annual compliance level, a facility that fails to meet its annual compliance level in any fiscal year shall, in the following year, develop and implement a plan of action that can reasonably be expected to enable the facility to meet its annual compliance level. Such actions may include special notice to the community through newspaper, radio, and television, or expansion of service to Category B, or, with respect to nursing homes, Category C, persons. The Secretary may require changes to the plan. Where a facility fails to comply with this section, the Secretary may require it to make up the deficit in the fiscal year following the year in which it was required to institute the plan.

(c) *Excesses.* (1) Except for facilities certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517, if a facility provides in a fiscal year uncompensated services in an amount exceeding its annual compliance level, it may apply the amount of excess to reduce its annual compliance level in any subsequent fiscal year. The facility may use any excess amount to reduce its annual compliance level only if the services in excess of the annual compliance level are provided in accordance with the requirements of this subpart.

(2) *Calculation and adjustment of excess.* (i) The amount of an excess in uncompensated services in any fiscal year is the difference between the amount of uncompensated services the facility provided in that year and the facility's annual compliance level for that year.

(ii) The amount of any excess compliance applied to reduce a facility's annual compliance level must be adjusted by a percentage equal to the percentage change in the CPI between the CPI available in the fiscal year in which the facility provided the excess, and the CPI available in the fiscal year in which the facility applies the excess to reduce its annual compliance level or satisfy its remaining obligation.

(3) Except as provided in subparagraph (1) of this paragraph, a facility assisted under title VI may in any fiscal year apply the amount of excess credited under this paragraph to satisfy the remainder of its obligation to provide uncompensated services. A facility's remaining obligation is determined as follows:

(i) Where the annual compliance level in such fiscal year is established under paragraph (a)(2) of this section, the remaining obligation is:

(A) For grant assistance, 10 percent of each grant under obligation, multiplied by the number of years remaining in its period of obligation, adjusted as provided for in paragraph (a)(2) of this section, plus any deficits required to be made up and less any unused excesses accrued in prior years; and

(B) For loan assistance, the facility's annual compliance level multiplied by the number of years remaining in the scheduled life of the loan, plus the sum of 10 percent of each yearly cumulative total of additional interest subsidy or other payments (which the Secretary will have made in connection with the guaranteed loan or a direct loan which has been sold) in each subsequent year remaining in the scheduled life of the loan, plus any deficits required to be made up, and less any unused excesses accrued in prior years; or

(ii) Where the annual compliance level in such fiscal year is established under paragraph (a)(1) of this section, the remaining obligation is the average of the facility's annual compliance levels in the previous three years, multi-

plied by the number of years remaining in its period of obligation, plus any deficits required to be made up under this section, and less any unused excesses accrued in prior years.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987, as amended at 60 FR 16756, Mar. 31, 1995; 66 FR 49266, Sept. 26, 2001]

§ 124.504 Notice of availability of uncompensated services.

(a) *Published notice.* A facility shall publish in a newspaper of general circulation in its area notice of its uncompensated services obligation before the beginning of its fiscal year. The notice shall include:

(1) The plan of allocation the facility proposes to adopt;

(2) The amount of uncompensated services the facility intends to make available in the fiscal year or a statement that the facility will provide uncompensated services to all persons unable to pay who request uncompensated services;

(3) An explanation, if the amount of uncompensated services the facility intends to make available in a fiscal year is less than the annual compliance level. If a facility has satisfied its remaining uncompensated services obligation since the last published notice under this paragraph, or will satisfy the remaining obligation during the fiscal year, the explanation must include this information; and

(4) A statement inviting interested parties to comment on the allocation plan.

(b) *Posted notice.* (1) The facility shall post notices, which the Secretary supplies in English and Spanish, in appropriate areas in the facility, including but not limited to the admissions areas, the business office, and the emergency room.

(2) If in the service area of the facility the "usual language of households" of ten percent or more of the population according to the most recent figures published by the Bureau of the Census is other than English or Spanish, the facility shall translate the notice into that language and post the translated notice on signs substantially similar in size and legibility to and posted with those supplied under paragraph (b)(1) of this section.

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(3) The facility shall make reasonable efforts to communicate the contents of the posted notice to persons who it has reason to believe cannot read the notice.

(c) *Individual written notice.* (1) In any period during a fiscal year in which uncompensated services are available in the facility, the facility shall provide individual written notice of the availability of uncompensated services to each person who seeks services in the facility on behalf of himself or another. The individual written notice must:

(i) State that the facility is required by law to provide a reasonable amount of care without or below charge to people who cannot afford care;

(ii) Set forth the criteria the facility uses for determining eligibility for uncompensated services (in accordance with the financial eligibility criteria and the allocation plan);

(iii) State the location in the facility where anyone seeking uncompensated services may request them; and

(iv) State that the facility will make a written determination of whether the person will receive uncompensated services, and the date by or period within which the determination will be made.

(2) The facility shall provide the individual written notice before providing services, except where the emergency nature of the services provided makes prior notice impractical. If this exception applies, the facility shall provide the individual written notice to the next of kin or to the patient as soon as practical, but not later than when first presenting a bill for services.

(3) The facility shall make reasonable efforts to communicate the contents of the individual written notice to persons who it has reason to believe cannot read the notice.

§ 124.505 Eligibility criteria.

(a) A person unable to pay for health services is a person who—

(1) Is not covered, or receives services not covered, under a third-party insurer or governmental program, except where the person is not covered because the facility fails to participate in a program in which it is required to participate by § 124.603(c);

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(2) Falls into one of the following categories:

(i) *Category A*—A person whose annual individual or family income, as applicable, is not greater than the current poverty line issued by the Secretary pursuant to 42 U.S.C. 9902 that applies to the individual or family. The facility shall provide uncompensated services to persons in Category A without charge.

(ii) *Category B*—A person whose annual individual or family income, as applicable, is greater than but not more than twice the poverty line issued by the Secretary pursuant to 42 U.S.C. 9902 that applies to the individual or family. If persons in Category B are included in the allocation plan, the facility shall provide uncompensated services to these persons without charge, or in accordance with a schedule of charges as specified in the allocation plan.

(iii) *Category C*—With respect only to persons seeking or receiving nursing home services, a person whose annual or family income, as applicable, is more than twice but not greater than three times the poverty line issued by the Secretary pursuant to 42 U.S.C. 9902 that applies to the individual or family. If persons in Category C are included in the allocation plan, the facility shall provide uncompensated services to these persons without charge, or in accordance with a schedule of charges as specified in the allocation plan; and

(3) Requests services within the facility's allocation plan in effect at the time of the request.

(b) For purposes of determining eligibility for uncompensated services, revisions of the poverty line are effective 60 days from the date of their publication in the FEDERAL REGISTER.

(c) A person is eligible for uncompensated services if the person's individual or family annual income, as applicable, is at or below the level established under paragraph (a)(2) of this section, when calculated by either of the following methods:

(1) Multiplying by four the person's or family's income, as applicable, for the three months preceding the request for uncompensated services;

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(2) Using the person's or family's income, as applicable, for the twelve months preceding the request for uncompensated services.

[52 FR 46031, Dec. 3, 1987, as amended at 60 FR 16756, Mar. 31, 1995]

§ 124.506 Allocation of services; plan requirement.

(a)(1) A facility shall provide its uncompensated services in accordance with a plan that sets out the method by which the facility will distribute its uncompensated services among persons unable to pay. The plan must:

(i) State the type of services that will be made available;

(ii) Specify the method, if any, for distributing those services in different periods of the year;

(iii) State whether Category B or, in the case of nursing homes only, Category C persons will be provided uncompensated services, and if so, whether the services will be available without charge or at a reduced charge;

(iv) If services will be made available to Category B persons at a reduced charge, specify the method used for reducing charges, and provide that the method is applicable to all persons in Category B;

(v) With respect to nursing homes only, if services will be made available to Category C persons at a reduced charge, specify the method used for reducing charges, provided that such method may not result in greater reductions than those afforded to Category B persons, and provide that this method is applicable to all persons in Category C; and

(vi) Provide that the facility provides uncompensated services to all persons eligible under the plan who request uncompensated services.

(2) A facility must adopt an allocation plan that meets the requirements of paragraph (a) by publishing the plan in a newspaper of general circulation in its area. The plan may take effect no earlier than 60 days following the date of publication.

(b)(1) If in any fiscal year a facility fails to adopt and publish a plan in accordance with paragraph (a) of this section, it shall provide uncompensated services in accordance with the last

plan it published in a newspaper of general circulation in its area.

(2) If no plan was previously published in accordance with paragraph (a)(2) of this section, the facility must provide uncompensated services without charge to all applicants in Category A and Category B, and, with respect to nursing homes, Category C, who request service in the facility. This requirement applies until the facility ceases to provide uncompensated services under § 124.508 or until an allocation plan published in accordance with paragraph (a)(2) of this section becomes effective.

(c) A facility may revise its allocation plan during the fiscal year by publishing the revised plan in a newspaper of general circulation in the area it serves. A revised plan may take effect no earlier than 60 days following the date of publication.

[52 FR 46031, Dec. 3, 1987, as amended at 60 FR 16756, Mar. 31, 1995]

§ 124.507 Written determinations of eligibility.

(a) Determinations of eligibility must be in writing, be made in accordance with this section, and a copy of the determination must be provided to the applicant promptly.

(b) *Content of determinations*—(1) *Favorable determinations*. A determination that an applicant is eligible must indicate:

(i) That the facility will provide uncompensated services at no charge or at a specified charge less than the allowable credit for the services;

(ii) The date on which services were requested;

(iii) The date on which the determination was made;

(iv) The applicant's individual or family income, as applicable, and family size; and

(v) The date on which services were or will be first provided to the applicant.

(2) *Conditional determinations*. (i) As a condition to providing uncompensated services, a facility may:

(A) Require the applicant to furnish any information that is reasonably necessary to substantiate eligibility; and

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(B) Require the applicant to apply for any benefits under third party insurer or governmental programs to which he/she is or could be entitled upon proper application.

(ii) A conditional determination must:

(A) Comply with paragraph (b)(1) of this section; and

(B) State the condition(s) under which the applicant will be found eligible.

(iii) When a facility determines that the condition(s) upon which a conditional determination was made has been met, or will not be met, it shall make a favorable determination or denial on the request, as appropriate, in accordance with this section.

(3) *Denials.* A facility must provide to each applicant denied the uncompensated services requested, in whole or in part, a dated statement of the reasons for the denial.

(c) *Timing of determinations—(1) Preservice determinations.* (i) Facilities other than nursing homes shall make a determination of eligibility within two working days following a request for uncompensated services which is made before receipt of outpatient services or before discharge for inpatient services;

(ii) Nursing homes shall make a determination of eligibility within ten working days, but no later than two working days following the date of admission, following a request for uncompensated services made prior to admission.

(2) *Postservice determinations.* All facilities shall make a determination of eligibility not later than the end of the first full billing cycle following a request for uncompensated services which is made after receipt of outpatient services, discharge for inpatient services, or admission for nursing home services.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

§ 124.508 Cessation of uncompensated services.

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517.* Where a facility, other than a facility certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517, has maintained the records required by

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§ 124.510(a) and determines based thereon that it has met its annual compliance level for the fiscal year or the appropriate level for the period specified in its allocation plan, it may, for the remainder of that year or period:

(1) Cease providing uncompensated services;

(2) Cease providing individual notices in accordance with § 124.504(c);

(3) Remove the posted notices required by § 124.504(b); and

(4) Post an additional notice stating that it has satisfied its obligation for the fiscal year or appropriate period and when additional uncompensated services will be available.

(b) *Facilities certified under § 124.514.* Where a facility certified under § 124.514 has maintained the records required by § 124.510(c) and determines based thereon that it has met its compliance level, under § 124.514(d), for the fiscal year, it may, for the remainder of the fiscal year:

(1) Cease providing uncompensated services; and

(2) Discontinue providing notice pursuant to § 124.514(b)(2).

[52 FR 46031, Dec. 3, 1987, as amended at 59 FR 44639, Aug. 30, 1994; 66 FR 49266, Sept. 26, 2001]

§ 124.509 Reporting requirements.

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517—(1) Timing of reports.* (i) A facility shall submit to the Secretary a report to assist the Secretary in determining compliance with this subpart once every three fiscal years, on a schedule to be prescribed by the Secretary.

(ii) A facility shall submit the required report more frequently than once every three years under the following circumstances:

(A) If the facility determines that in the preceding fiscal year it did not provide uncompensated services at the annual compliance level, it shall submit a report.

(B) If the Secretary determines, and notifies the facility in writing that a report is needed for proper administration of the program, the facility shall submit a report within 90 days after receiving notice from the Secretary, or

within 90 days after the close of the fiscal year, whichever is later.

(iii) Except as specified in paragraph (a)(1)(ii)(B) of this section, the reports required by this section shall be submitted within 90 days after the close of the fiscal year, unless a longer period is approved by the Secretary for good cause.

(2) *Content of report.* The report must include the following information in a form prescribed by the Secretary:

(i) Information that the Secretary prescribes to permit a determination of whether a facility has met the annual compliance level for the fiscal years covered by the report;

(ii) The date on which the notice required by § 124.504(a) was published, and the name of the newspaper that printed the notice;

(iii) If the amount of uncompensated services provided by the facility in the preceding fiscal year was lower than the annual compliance level, an explanation of why the facility did not meet the required level. If the facility claims that it failed to meet the required compliance level because it was financially unable to do so, it shall explain and provide documentation prescribed by the Secretary;

(iv) If the facility is required to submit an affirmative action plan, a copy of the plan.

(v) Other information that the Secretary prescribes.

(3) *Institution of suit.* Not later than 10 days after being served with a summons or complaint the facility shall notify the HHS Regional Health Administrator¹ for the Region in which it is located of any legal action brought against it alleging that it has failed to comply with the requirements of this subpart.

(b) *Facilities certified under § 124.513 or § 124.516.* A facility certified under § 124.513 or § 124.516 shall comply with paragraph (a)(3) of this section and shall submit within 90 days after the close of its fiscal year, as appropriate:

(1) A certification, signed by the responsible official of the facility, that there has been no material change in

the factors upon which the certification was based; or

(2) A certification, signed by the responsible official of the facility and supported by appropriate documentation, that there has been a material change in the factors upon which the certification was based.

(c) *Facilities certified under § 124.514.* A facility certified under § 124.514 shall comply with paragraph (a)(3) of this section and shall submit within 90 days after the close of its fiscal year, as appropriate:

(1)(i) A certification, signed by the responsible official of the facility, that there has been no material change in the factors upon which the certification was based; or

(ii) A certification, signed by the responsible official of the facility and supported by appropriate documentation, that there has been a material change in the factors upon which the certification was based; and

(2) A certification, signed by the responsible official of the facility, of the amount of uncompensated services provided in the previous fiscal year.

(d) *Facilities certified under § 124.515.* A facility certified under § 124.515 shall submit such reports as are required by the terms of its grant under section 329 or 330 or by its agreement under section 334 of the Act, as applicable, at such intervals as the Secretary may require.

(e) *Facilities certified under § 124.517.* If a facility certified under § 124.517 ceases to provide uncompensated services consistent with its certification under that section because of financial inability, it shall report such cessation to the Secretary within 90 days of the cessation and provide any documentation or information relating to the provision or cessation of uncompensated services that the Secretary may require.

(Approved by the Office of Management and Budget under control number 0915-0077)

[52 FR 46031, Dec. 3, 1987, as amended at 52 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989; 59 FR 44639, Aug. 30, 1994; 66 FR 49266, Sept. 26, 2001]

¹The addresses of the HHS Regional Offices are set out in 45 CFR 5.31.

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§ 124.510 Record maintenance requirements.

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517.* (1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance with the requirements of this subpart in any fiscal year, including:

(i) Any documents from which the information required to be reported under § 124.509(a) was obtained;

(ii) Accounts which clearly segregate uncompensated services from other accounts; and

(iii) Copies of written determinations of eligibility under § 124.507.

(2) A facility shall retain the records maintained pursuant to paragraph (a)(1) for three years after submission of the report required by § 124.509(a)(1), except where a longer period is required by the Secretary, or until 180 days following the close of the Secretary's assessment investigation under § 124.511(b), whichever is less.

(3) A facility shall, within 60 days of the end of each fiscal year, determine the amount of uncompensated services it provided in that fiscal year. Documents that support the facility's determination shall be made available to the public on request. If a report is or will be filed under § 124.509(a)(1), a facility may respond to a request by providing a copy of the report to the requester.

(b) *Facilities certified under § 124.513, § 124.514, § 124.516, or § 124.517.* A facility certified under § 124.513, § 124.514, § 124.516, or § 124.517 shall retain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request any records necessary to document compliance with the applicable requirements of this subpart in any fiscal year, including those documents provided to the Secretary under § 124.513(c), § 124.514(c), § 124.516(c), or § 124.517(b), as applicable. A facility shall maintain these records for three years, except where a longer period is required as a result of an investigation by the Secretary. In such cases, records must be kept until 180 days following the close

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of the Secretary's assessment investigation under § 124.511(b).

(c) *Facilities certified under § 124.515.* A facility certified under § 124.515 shall maintain the records required by its grant under section 329 or section 330 or its agreement under section 334 of the Act, as applicable, for such period of time as the grant agreement may require.

(Information collection requirements in paragraphs (a) and (b) approved by the Office of Management and Budget under control number 0915-0103)

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987; 59 FR 44639, Aug. 30, 1994; 66 FR 49266, Sept. 26, 2001]

§ 124.511 Investigation and determination of compliance.

(a) *Complaints.* A complaint that a facility is out of compliance with the requirements of this subpart may be filed with the Secretary by any person.

(1) A complaint is considered to be filed with the Secretary on the date the following information is received in the Office of the HHS Regional Health Administrator for the Region in which the facility is located:

(i) The name and address of the person making the complaint or on whose behalf the complaint is made;

(ii) The name and location of the facility;

(iii) The date or approximate date on which the event occurred; and

(iv) A statement of what actions the complainant considers to violate the requirements of this subpart.

(2) The Secretary promptly provides a copy of the complaint to the facility named in the complaint.

(3) When the Secretary investigates a facility, the facility, including a facility certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517, shall provide to the Secretary on request any documents, records and other information concerning its operation that relate to the requirements of this subpart. A facility will be presumed to be out of compliance with its assurance unless it supplies documentation sufficient to show compliance with the applicable provisions of this subpart.

(4) Section 1627 of the Act provides that if the Secretary dismisses a complaint or the Attorney General has not

brought an action for compliance within six months from the date on which the compliant is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he/she will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, the Secretary may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the applicant, dismiss the complaint without a finding as to compliance prior to the end of the six month period, but no earlier than 45 days after the complaint is filed.

(b) *Assessments.* The Secretary periodically investigates and assesses facilities to ascertain compliance with the requirements of this subpart, including certification of the amount of uncompensated services provided in a fiscal year or years, and provides guidance and prescribes corrective action to correct noncompliance.

(1) *Compliance after February 1, 1988.* (i) The Secretary may certify that a facility has substantially complied with its assurance for a fiscal year or years, and such certification shall establish that the facility provided the amount of uncompensated services certified for the period covered by the certification.

(ii) A certification of substantial compliance shall be based on the amount properly claimed by the facility pursuant to §124.509(a), utilizing procedures determined by the Secretary to be sufficient to establish that the facility has substantially complied with its assurance for the period covered by the certification. The procedures will include examination of individual account data to the extent deemed necessary by the Secretary.

(iii) A certification of substantial compliance will be made where the Secretary determines that, for the period covered by the certification, the facility provided uncompensated services to eligible persons who had equal opportunity to apply therefor. In making this determination, the Secretary will consider, in descending order of importance, whether—

(A) Corrective action prescribed pursuant to §124.512(b) has been taken by the facility;

(B) Any noncompliance with the requirements of this subpart may be remedied by corrective action under §124.512(b);

(C) The facility had procedures in place that complied with the requirements of §124.504(c), §124.505, §124.507, §124.509, §125.510, §124.513(b)(2), §124.514(b)(2), §124.515, §124.516(b)(1) or (b)(2), as applicable, or §124.517(b), and systematically and correctly followed such procedures.

(2) *Compliance prior to February 1, 1988.* The Secretary will determine the amount of creditable services provided prior to the effective date of these rules using the compliance standards applicable under the rules as promulgated on May 18, 1979, based on procedures determined by the Secretary to be sufficient to establish that the facility provided such amounts of uncompensated services in the period(s) being assessed.

(c) *Determinations of financial inability.* In determining whether a facility was or is financially able to meet its annual compliance level, the Secretary will consider any comments submitted by interested parties. In making this determination, the Secretary will consider factors such as:

- (1) The ratio of revenues to expenses;
- (2) The occupancy rate;
- (3) The ratio of current assets to current liabilities;
- (4) The average cost per patient day;
- (5) The number of days of operating expenses in accounts payable;
- (6) The number of days of revenues in accounts receivable;
- (7) The sinking fund (or depreciation fund) balance;
- (8) The debt coverage ratio; and
- (9) The availability of restricted or unrestricted funds (such as an endowment) available for charitable use.

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987; 53 FR 5576, Feb. 25, 1988; 59 FR 44639, Aug. 30, 1994; 66 FR 49266, Sept. 26, 2001]

§ 124.512 Enforcement.

(a) If the Secretary finds, based on his/her investigation under §124.511, that a facility did not comply with the

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requirements of this subpart, the Secretary may take any action authorized by law to secure compliance, including but not limited to, voluntary agreement or a request to the Attorney General to bring an action against the facility for specific performance.

(b) A facility, including a facility certified under § 124.513, § 124.514, § 124.516, or § 124.517, that has denied uncompensated services to any person because it failed to comply with the requirements of this subpart will not be in compliance with its assurance until it takes whatever steps are necessary to remedy fully the noncompliance, including:

- (1) Provision of uncompensated services to applicants improperly denied;
- (2) Repayment of amounts improperly collected from persons eligible to receive uncompensated services; and
- (3) Other corrective actions prescribed by the Secretary.

(c) The Secretary may disallow all of the uncompensated services claimed in a fiscal year where the Secretary finds that the facility was in substantial noncompliance with its assurance because it failed to:

- (1) Have a system for providing notice to eligible persons as required by § 124.504(c), § 124.513(b)(2), § 124.514(b)(2), § 124.516 (b)(2)(ii)(A), or § 124.517(b)(2), as applicable;
- (2) Comply with the applicable reporting requirements of § 124.509;
- (3) Have a system for maintaining records of uncompensated services provided in accordance with § 124.510; or
- (4) Take corrective action prescribed pursuant to paragraph (b) of this section.

(d) In the absence of a finding of substantial compliance or substantial noncompliance in a fiscal year, the Secretary may disallow uncompensated services claimed by a facility in that fiscal year to the extent that the Secretary finds that such services are not documented as uncompensated services under § 124.510 or are subject to disallowance under § 124.513(d) or § 124.514(d), as applicable.

[52 FR 46031, Dec. 3, 1987, as amended at 59 FR 44639, Aug. 30, 1994; 66 FR 49266, Sept. 26, 2001]

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§ 124.513 Public facility compliance alternative.

(a) *Effect of certification.* The Secretary may certify a facility which meets the requirements of paragraphs (b) and (c) of this section as a "public facility". A facility which is so certified is not required to comply with this subpart except as otherwise herein provided.

(b) *Criteria for qualification.* A public facility may qualify for certification under this section if all of the following criteria are met:

(1) It is a facility which is owned and operated by a unit of State or local government or a quasi-public corporation as defined at 42 CFR 124.2(m).

(2) It provides health services without charge or at a substantially reduced rate to persons who are determined by the facility to qualify therefor under a program of discounted health services. A "program of discounted health services" must provide for financial and other objective eligibility criteria and procedures, including notice prior to nonemergency service, that assure effective opportunity for all persons to apply for and obtain a determination of eligibility for such services, including a determination prior to service where requested; *provided that*, such criteria and procedures are not required where the facility makes all services available to all persons at no or nominal charge.

(3)(i) It received, for the three most recent fiscal years, at least 10 percent of its total operating revenue (net patient revenue plus other operating revenue, exclusive of any amounts received, or if not received, claimed, as reimbursement under titles XVIII and XIX of the Social Security Act) from State and local tax appropriations or other State and local government revenues, or from a quasi-public corporation as defined at 42 CFR 124.2(m), to cover operating deficits attributable to the provision of discounted services; or

(ii) If provided, in each of the three most recent fiscal years, uncompensated services under this subpart or under programs described by the documentation provided under § 124.513(c)(2) in an amount not less than twice the annual compliance level computed under § 124.503(a).

(c) *Procedures for certification.* To be certified under this section, a facility must submit to the Secretary, in addition to other materials that the Secretary may from time to time require, copies of the following:

(1) Audited financial statements or official State or local government documents (such as annual reports or budget documents), for the three most recent fiscal years, sufficient to show that the facility meets the criteria in paragraph (b)(3)(i) or (ii) of this section.

(2) A complete description of its program(s) of discounted health services, including charging and collection policies of the facility, and eligibility criteria and notice and determination procedures used under its program(s) of discounted services.

(d) *Period of effectiveness.* (1) A certification by the Secretary under this section remains in effect until withdrawn. The Secretary may disallow credit under this subpart when the Secretary determines that there has been a material change in any factor upon which certification was based or substantial noncompliance with this subpart. The Secretary may withdraw certification where the change or noncompliance has not been adequately remedied or otherwise continues.

(2) *Deficits*—(i) *Title VI-assisted facilities with assessed deficits.* Where a facility assisted under title VI of the Act has been assessed as having a deficit under § 124.503(b) that has not been made up prior to certification under this section, the facility may make up that deficit by either—

(A) Demonstrating to the Secretary's satisfaction, that it met the requirements of paragraph (b) of this section for each year in which a deficit was assessed; or

(B) Providing an additional period of service under this section on the basis of one (or portion of a) year of certification for each year (or portion of a year) of deficit assessed. The period of obligation applicable to the facility under § 124.501(b) shall be extended until the deficit is made up in accordance with the preceding sentence.

(ii) *Title VI-assisted facilities which have not been assessed.* Where any period of compliance under this subpart

of a facility assisted under title VI of the Act has not been assessed, the facility will be presumed to have no allowable credit for such period. The facility may either—

(A) Make up such deficit in accordance with paragraph (d)(2)(i) of this section; or

(B) Submit an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (d)(2)(i) of this section.

(iii) *Title XVI-assisted facilities.* (A) A facility assisted under title XVI of the Act which has an assessed deficit which was not made up prior to certification under this section shall make up that deficit in accordance with paragraph (d)(2)(i)(A) of this section. If it cannot make the showing required by that paragraph, it shall make up the deficit when its certification under this section is withdrawn.

(B) A facility assisted under title XVI of the Act whose compliance with this subpart has not been completely assessed will be presumed to have no allowable credit for the unassessed period. The facility may make up the deficit by—

(1) Following the procedure of subparagraph (d)(2)(iii)(A) of this section; or

(2) Submitting an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (d)(2)(iii)(A) of this section.

(Approved by the Office of Management and Budget under control number 0915-0103)

[52 FR 46031, Dec. 3, 1987; 52 FR 48362, Dec. 21, 1987]

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§ 124.514 Compliance alternative for facilities with small annual obligations.

(a) *Effect of certification.* The Secretary may certify a facility which meets the requirements of paragraphs (b) and (c) of this section as a "facility with a small annual obligation." A facility which is so certified is not required to comply with this subpart except as otherwise herein provided.

(b) *Criteria for qualification.* A facility may qualify for certification under this section if all of the following criteria are met:

(1)(i) Title VI-assisted facilities. (A) For the facility's fiscal year in which this section becomes effective, the level, computed under § 124.503(c) (3), divided by the number of years remaining in its period of obligation (including an additional year or portion of a year for each year or portion of a year in which a deficit was incurred and has not been made up), is not more than \$10,000;

(B) For a subsequent fiscal year, the level computed under paragraph (A) of this paragraph (b)(1)(i), is at or less than \$10,000, adjusted by a percentage equal to the percentage change in the CPI available in the year in which this section becomes effective and the most recent year for which a published index is available.

(ii) *Title XVI-assisted facilities.* (A) For the facility's fiscal year in which this section becomes effective, the level under § 124.503(a), plus the amount of any noncompliance deficits which have not been made up, is at or less than \$10,000.

(B) For a subsequent fiscal year, the level, computed under paragraph (A) of this paragraph (b)(1)(ii), is at or less than \$10,000, adjusted as provided in paragraph (b)(1)(i)(B) of this section.

(2) It provides health services without charge or at a substantially reduced rate to persons who are determined by the facility to qualify therefor under a program of discounted health services. A "program of discounted health services" must provide for financial and other objective eligibility criteria and procedures, including notice prior to nonemergency service, that assure effective opportunity for all persons to apply for and

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obtain a determination of eligibility for such services, including a determination prior to service where requested; *Provided that*, such criteria and procedures are not required where the facility makes all services available to all persons at no or nominal charge.

(c) *Procedures for certification.* To be certified under this section, a facility must submit to the Secretary, in addition to other materials that the Secretary may from time to time require, a complete description of its program(s) of discounted health services, including charging and collection policies of the facility, and eligibility criteria and notice and determination procedures used under its program(s) of discounted services.

(d) *Period of effectiveness.* A certification by the Secretary under this section remains in effect until withdrawn. During the period in which such certification is in effect, the facility must provide uncompensated services in an amount not less than the level applicable under paragraph (b)(1) of this section for each fiscal year. The Secretary may disallow credit under this subpart when the Secretary determines that there has been a material change in any factor upon which certification was based or substantial noncompliance with this subpart. The Secretary may withdraw certification where the change or noncompliance cannot be or has not been adequately remedied or noncompliance otherwise continues.

(e) *Deficits.* (1) Where the compliance level of a facility assisted under title VI of the Act is computed under paragraph (b)(1)(i)(A) of this section as including additional year(s) or a portion of a year, the facility's period of obligation under this subpart shall be extended by such additional period, until certification is withdrawn.

(2) Where a facility has been assessed as having a deficit under § 124.503(b) that has not been made up prior to withdrawal of certification under this section or fails to provide services as required by paragraph (d) of this section, the facility must make up the

deficit in accordance with § 124.503(b) following withdrawal of certification.

(Approved by the Office of Management and Budget under control number 0915-0077)

[52 FR 46031, Dec. 3, 1987, as amended at 52 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989]

§ 124.515 Compliance alternative for community health centers, migrant health centers and certain National Health Service Corps sites.

(a) *Period of effectiveness.* For each fiscal year for which a facility that receives a grant to operate a community health center under section 330 of the Act or a migrant health center under section 329 of the Act is in substantial compliance with the terms and conditions of such grant relating to the provision of services at a discount, the facility shall be certified as having met its annual compliance level in accordance with the requirements of this subpart and shall not be required otherwise to comply with the requirements of this subpart for that fiscal year. This provision also applies to any facility that has signed a memorandum of agreement with the Secretary under section 334 of the Act if the services provided by the National Health Service Corps professional(s) assigned pursuant to that agreement constitute all of the medical services provided by the facility.

(b) *Deficits*—(1) *Title VI-assisted facilities with assessed deficits.* Where a facility assisted under title VI of the Act has been assessed as having a deficit under § 124.503(b) that has not been made up prior to certification under this section, the facility may make up that deficit by either—

(i) Demonstrating to the Secretary's satisfaction that it met the requirements of paragraph (a) of this section for each year in which a deficit was assessed; or

(ii) Providing an additional period of service under this section on the basis of one (or portion of a) year of certification for each year (or portion of a year) of deficit assessed. The period of obligation applicable to the facility under § 124.501(b) shall be extended until the deficit is made up in accordance with the preceding sentence.

(2) *Title VI-assisted facilities which have not been assessed.* Where any period of compliance under this subpart of a facility assisted under title VI of the Act has not been assessed, the facility will be presumed to have no allowable credit for such period. The facility may either—

(i) Make up such deficit in accordance with paragraph (b)(1) of this section; or

(ii) Submit an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (b)(1) of this section.

(3) *Title XVI-assisted facilities.* (i) A facility assisted under title XVI of the Act which has an assessed deficit which was not made up prior to certification under this section shall make up that deficit in accordance with paragraph (b)(1)(i) of this section. If it cannot make the showing required by that paragraph, it shall make up the deficit when it is no longer certified under this section.

(ii) A facility assisted under title XVI of the Act whose compliance with this subpart has not been completely assessed will be presumed to have no allowable credit for the unassessed period. The facility may make up the deficit by—

(A) Following the procedure of paragraph (b)(3)(i) of this section; or

(B) Submitting an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made

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up in accordance with paragraph (b)(3)(i) of this section.

(Approved by the Office of Management and Budget under control number 0915-0077)

[52 FR 46031, Dec. 3, 1987, as amended at 52 FR 48362, Dec. 21, 1987; 54 FR 52939, Dec. 26, 1989]

§ 124.516 Charitable facility compliance alternative.

(a) *Effect of certification.* The Secretary may certify as a "charitable facility" a facility which meets the applicable requirements of this section. A facility which is certified or provisionally certified as a charitable facility is not required to comply with this subpart except as provided in this section.

(b) *Methods of qualification for certification or provisional certification.* (1) A facility may qualify for certification under this section if it meets the criteria of paragraph (c)(1) or paragraph (c)(2) of this section.

(2) A facility may qualify for a provisional certification under this section if it provides an assurance that meets the requirements of paragraph (d)(2) of this section.

(c) *Criteria for certification under paragraph (b)(1) of this section.* A facility may qualify for certification under paragraph (b)(1) of this section if it met the criteria of either paragraph (c)(1) or paragraph (c)(2) of this section for the fiscal year preceding the request for certification. A facility that seeks certification under paragraph (c)(2) of this section must also meet the requirements of paragraph (c)(2)(i) or paragraph (c)(2)(ii) of this section during each year of certification.

(1)(i) *For facilities that are nursing homes:* It received no monies directly from patients with incomes up to triple the current poverty line issued by the Secretary pursuant to 42 U.S.C. 9902, exclusive of amounts charged or received for purposes of claiming reimbursement under third party insurance or governmental programs, such as Medicaid or Medicare deductible or coinsurance amounts.

(ii) *For all other facilities.* It received no monies directly from patients with incomes up to double the current poverty line issued by the Secretary pursuant to 42 U.S.C. 9902, exclusive of amounts charged or received for pur-

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poses of claiming reimbursement under third party insurance or governmental programs, such as Medicaid or Medicare deductible or coinsurance amounts.

(2) It received at least 10 percent of its total operating revenue (net patient revenue plus other operating revenue, exclusive of any amounts received, or if not received, claimed, as reimbursement under Medicaid or Medicare) from philanthropic sources to cover operating deficits attributable to the provision of discounted services. Philanthropic sources include private trusts, foundations, churches, charitable organizations, state and/or local funding, and individual donors; and either—

(i) Provides health services without charge or at a substantially reduced rate (exclusive of amounts charged or received for purposes of claiming reimbursement under third party insurance or governmental programs, such as Medicaid or Medicare deductible or coinsurance amounts) to persons who are determined by the facility to qualify for such reduced charges under a program of discounted health services. A "program of discounted health services" must provide for financial and other objective eligibility criteria and procedures, including notice prior to nonemergency service, that assure effective opportunity for all persons to apply for and obtain a determination of eligibility for such services, including a determination prior to service where requested; or

(ii) Makes all services of the facility available to all persons at no more than a nominal charge, exclusive of amounts charged or received for purposes of claiming reimbursement under third party insurance or governmental programs, such as Medicaid or Medicare deductible or coinsurance amounts.

(d) *Procedures for certification—(1) Certification under paragraph (b)(1) of this section.* To be certified under paragraph (b)(1) of this section, a facility must submit to the Secretary, in addition to other materials that the Secretary may from time to time require, copies of the following:

(i) An audited financial statement for the fiscal year preceding the request or

other documents prescribed by the Secretary, sufficient to show that the facility meets the criteria of paragraph (c)(1) or (c)(2) of this section, as applicable;

(ii) Where a facility claims qualification under paragraph (c)(2)(i) of this section, a complete description, and documentation where requested, of its program of discounted health services, including charging and collection policies of the facility, and eligibility criteria and notice and determination procedures used under its program(s) of discounted health services;

(iii) Where the facility claims qualification under paragraph (c)(1) or paragraph (c)(2)(ii) of this section, a complete description, and documentation where requested, of its admission, charging, and collection policies.

(2) *Provisional certification under paragraph (b)(2) of this section.* (i) In order to receive a provisional certification under paragraph (b)(2) of this section, prior to the beginning of the fiscal year for which provisional certification will be sought, the facility must submit to the Secretary an assurance, together with such documentation and in such form and manner as the Secretary may require, that it will operate during the fiscal year a program that qualifies for certification under paragraph (b)(1) of this section.

(ii) No later than 90 days following the end of the fiscal year in which a facility has operated a provisionally certified program, the facility must submit to the Secretary, the documentation required, as applicable, under paragraph (d)(1) of this section.

(e) *Period of effectiveness—(1) Certification under paragraph (b)(1) of this section.* A certification by the Secretary under paragraph (b)(1) of this section remains in effect until withdrawn. The Secretary may disallow credit under this subpart when the Secretary determines that there has been a material change in any factor upon which certification was based or substantial noncompliance with this section. The Secretary may withdraw certification where the change or noncompliance has not been, in the Secretary's judgment, adequately remedied or otherwise continues.

(2) *Provisional certification under paragraph (b)(2) of this section.* Where the Secretary is satisfied, based on the documentation submitted by the facility in accordance with paragraph (d)(2)(ii) of this section and any other information available to the Secretary, that the facility has complied with the terms of its provisional certification under paragraph (b)(2) of this section, the Secretary shall certify the facility under paragraph (b)(1) of this section. If the Secretary finds that the facility has not complied with the terms of its provisional certification under paragraph (b)(2) of this section, the facility will receive no credit towards its uncompensated services obligation during the fiscal year of provisional certification.

(f) *Deficits—(1) Title VI-assisted facilities—(i) Title VI-assisted facilities with assessed deficits.* Where a facility assisted under title VI of the Act has been assessed as having a deficit under § 124.503(b) that has not been made up prior to certification under paragraph (b)(1) of this section, the facility may make up that deficit by either—

(A) Demonstrating to the Secretary's satisfaction that it met the applicable requirements of paragraph (c) of this section for each year in which a deficit was assessed; or

(B) Providing an additional period of service under this section on the basis of one year (or portion of a year) of certification for each year (or portion of a year) of deficit assessed. The period of obligation applicable to the facility under § 124.501(b) shall be extended until the deficit is made up in accordance with the preceding sentence.

(ii) *Title VI-assisted facilities with unassessed deficits.* Where any period of compliance under this subpart of a facility assisted under title VI of the Act has not been assessed, the facility will be presumed to have no allowable credit for the unassessed period. The facility may either—

(A) Make up such deficit in accordance with paragraph (f)(1)(i) of this section; or

(B) Submit an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained

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pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (f)(1)(i)(B) of this section.

(2) *Title XVI-assisted facilities*—(i) *Title XVI-assisted facilities with assessed deficits*. A facility assisted under title XVI of the Act which has an assessed deficit which was not made up prior to certification under paragraph (b)(1) of this section shall make up that deficit in accordance with paragraph (f)(1)(i) of this section. If it cannot make the showing required by that paragraph, it shall make up the deficit when its certification under paragraph (b)(1) of this section is withdrawn.

(ii) *Title XVI-assisted facilities with unassessed deficits*. Where any period of compliance under this subpart of a facility assisted under title XVI of the Act has not been assessed, the facility will be presumed to have no allowable credit for the unassessed period. The facility may either—

(A) Make up such deficit in accordance with paragraph (f)(1)(i) of this section; or

(B) Submit an independent certified audit, conducted in accordance with procedures specified by the Secretary, of the facility's records maintained pursuant to § 124.510. If the audit establishes to the Secretary's satisfaction that no, or a lesser, deficit exists for the period in question, the facility will receive credit for the period so justified. Any deficit which the Secretary determines still remains must be made up in accordance with paragraph (f)(2)(i) of this section.

[66 FR 49267, Sept. 26, 2001]

§ 124.517 Unrestricted availability compliance alternative for Title VI-assisted facilities.

(a) *Effect of certification*. The Secretary may certify a Title VI-assisted facility which meets the requirements of paragraph (b) of this section and the applicable requirements of this subpart as an unrestricted availability facility. A facility which is so certified is not required to comply with the require-

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ments of this subpart, except as provided in this section or elsewhere in this subpart.

(b) *Criteria for qualification*. A facility may qualify for certification under this section if, for any fiscal year for which certification is sought, it operates a compliant, fully expanded uncompensated services program. Such a program must meet the following criteria:

(1) It makes all services of the facility available without charge to all persons requesting uncompensated services from the facility who are eligible under § 124.505, including all persons coming within Category B and, if applicable, Category C.

(2) It complies with the notice and allocation plan requirements of §§ 124.504 and 124.506, except that all notices published or provided must describe an allocation plan and program consistent with paragraph (b)(1) of this section.

(3) It makes written determinations in accordance with § 124.507, except that all favorable determinations must indicate that the facility will provide uncompensated services at no charge.

(4) It provides uncompensated services consistent with the requirements of this section for the entire fiscal year for which certification is sought, except that a facility may

(i) Cease providing such services and still receive credit, calculated in accordance with paragraph (d) of this section, where—

(A) The facility has completed its total uncompensated services obligation, including making up any deficit; or

(B) The facility determines, and submits documentation which the Secretary finds, taking into account the factors identified in § 124.511(c), sufficient to establish that it is financially unable to continue to meet the requirements of this section for the remainder of the fiscal year; and

(ii) Receive a portion of a year's credit for the first partial year in which it began operating a fully expanded program, as long as it continued to operate the fully expanded program in subsequent years.

(c) *Period of effectiveness*. A certification by the Secretary under this section remains in effect until withdrawn.

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The Secretary may withdraw certification under this section where the Secretary determines the facility is in substantial noncompliance with the requirements of paragraph (b) of this section and has not adequately remedied or otherwise continues such noncompliance. Where the Secretary withdraws certification for part or all of a fiscal year or years, no credit may be granted for the period of unremedied substantial noncompliance.

(d) *Deficits.* (1) Where a Title VI-assisted facility has been assessed as having a deficit under § 124.503(b) that has not been made up prior to certification under this section, the facility may make up the deficit by providing uncompensated services in accordance with this section. The facility shall receive credit towards its deficit on the basis of one year, or part thereof, of credit towards each "deficit year" for each year, or part thereof, of operation in compliance with this section and the applicable requirements of this subpart.

(2) The number of "deficit years" of a facility shall be calculated as follows:

(i) Determine the number of years in the facility's total period of obligation pursuant to § 124.501;

(ii) Subtract the number of years in which the facility operated in compliance with this section and the applicable requirements of this subpart from the number of years derived under paragraph (d)(2)(i) of this section;

(iii) For all years in which the facility did not operate in compliance with this section, determine the ratio of the total compliance levels applicable under § 124.503(a) to the facility's total deficit under § 124.503(b);

(iv) Multiply the percentage derived under paragraph (d)(2)(iii) of this section by the number of years under obligation pursuant to § 124.501 but for which the facility did not operate in compliance with this section;

(v) Subtract the number derived under paragraph (d)(2)(iv) of this section from the number of years derived under paragraph (d)(2)(ii) of this section;

(vi) If the facility is still within the period described in § 124.501(b)(1), add the number of years derived under paragraph (d)(2)(v) of this section to

the end of the period of obligation, or if the facility is beyond the period described in § 124.501(b)(1), add the number of years derived under paragraph (d)(2)(v) of this section to the last year the facility operated in compliance with this section.

[66 FR 49268, Sept. 26, 2001]

§ 124.518 Agreements with State agencies.

(a) Where the Secretary finds that it will promote the purposes of this subpart and the State agency is able and willing to do so, the Secretary may enter into an agreement with an agency of a State to assist in administering this subpart in the State. An agreement may be terminated by the Secretary or the State agency on 60 days notice.

(b) Under an agreement the State agency will provide any assistance the Secretary requests in any one or more of the following areas, as set out in the agreement:

(1) Investigation of complaints regarding noncompliance;

(2) Monitoring compliance of facilities with the requirements of this subpart;

(3) Review of reports submitted under § 124.509, including affirmative action plans;

(4) Making initial decisions for the Secretary with respect to compliance, subject to appeal by any party to the Secretary, or review by the Secretary on the Secretary's initiative; and

(5) Application of any sanctions available to it under State law (such as license revocation or termination of State assistance) against facilities determined to be out of compliance with the requirements of this subpart.

(c) Nothing in this subpart precludes any State from taking any action authorized by State law regarding the provision of uncompensated services by facilities in the State as long as the action taken does not prevent the Secretary from enforcing the requirements of this subpart.

[52 FR 46031, Dec. 3, 1987. Redesignated at 59 FR 44639, Aug. 30, 1994]

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Subpart G—Community Service

AUTHORITY: Secs. 215, 1525, 1602(6), Public Health Service Act as amended; 58 Stat 690, 88 Stat. 2249, 2259; 42 U.S.C. 216, 300m-4, 300o-1(6).

SOURCE: 44 FR 29379, May 18, 1979, unless otherwise noted.

§ 124.601 Applicability.

The provisions of this subpart apply to any recipient of Federal assistance under title VI or XVI of the Public Health Service Act that has given an assurance that it would make the facility or portion thereof assisted available to all persons residing (and, in the case of title XVI assisted applicants, employed), in the territorial area it serves. This assurance is referred to in this subpart as the "community service assurance."

§ 124.602 Definitions.

As used in this subpart:

Act means the Public Health Service Act, as amended.

Facility means the an entity that received assistance under title VI or title XVI of the Act and provided a community service assurance.

Fiscal year means facility's fiscal year.

Secretary means the Secretary of Health and Human Services or his delegatee.

Service area means the geographic area designated as the area served by the facility in the most recent State plan approved by the Secretary under title VI, except that, at the request of the facility, the Secretary may designate a different area proposed by the facility when he determines that a different area is appropriate based on the criteria in 42 CFR 53.1(d).

State agency means the agency of a state fully or conditionally designated by the Secretary as the State health planning and development agency of the State under section 1521 of the Act.

§ 124.603 Provision of services.

(a) *General.* (1) In order to comply with its community service assurance, a facility shall make the services provided in the facility or portion thereof constructed, modernized, or converted with Federal assistance under title VI

or XVI of the Act available to all persons residing (and, in the case of facilities assisted under title XVI of the Act, employed) in the facility's service area without discrimination on the ground of race, color, national origin, creed, or any other ground unrelated to an individual's need for the service or the availability of the needed service in the facility. Subject to paragraph (b) (concerning emergency services) a facility may deny services to persons who are unable to pay for them unless those persons are required to be provided uncompensated services under the provisions of Subpart F.

(2) A person is residing in the facility's service area for purposes of this section if the person:

(i) Is living in the service area with the intention to remain there permanently or for an indefinite period;

(ii) Is living in the service area for purposes of employment; or

(iii) Is living with a family member who resides in the service area.

(b) *Emergency services.* (1) A facility may not deny emergency services to any person who resides (or, in the case of facilities assisted under title XVI of the Act, is employed) in the facility's service area on the ground that the person is unable to pay for those services.

(2) A facility may discharge a person that has received emergency services, or may transfer the person to another facility able to provide necessary services, when the appropriate medical personnel determine that discharge or transfer will not subject the person to a substantial risk of deterioration in medical condition.

(c) *Third party payor programs.* (1) The facility shall make arrangements, if eligible to do so, for reimbursement for services with:

(i) Those principal State and local governmental third-party payors that provide reimbursement for services that is not less than the actual costs, as determined in accordance with accepted cost accounting principles; and

(ii) Federal governmental third-party programs, such as medicare and medicaid.

(2) The facility shall take any necessary steps to insure that admission

to and services of the facility are available to beneficiaries of the governmental programs specified in paragraph (c)(1) of this section without discrimination or preference because they are beneficiaries of those programs.

(d) *Exclusionary admissions policies.* A facility is out of compliance with its community service assurance if it uses an admission policy that has the effect of excluding persons on a ground other than those permitted under paragraph (a) of this section. Illustrative applications of this requirement are described in the following paragraphs:

(1) A facility has a policy or practice of admitting only those patients who are referred by physicians with staff privileges at the facility. If this policy or practice has the effect of excluding persons who reside (or for title XVI facilities, are employed) in the community from the facility because they do not have a private family doctor with staff privileges at the facility, the facility would not be in compliance with its assurance. The facility is not required to abolish its staff physician admissions policy as a usual method for admission. However, to be in compliance with its community service assurance it must make alternative arrangements to assist area residents who would otherwise be unable to gain admission to obtain services available in the facility. Examples of alternative arrangements a facility might use include:

(i) Authorizing the individual's physician, if licensed and otherwise qualified, to treat the patient at the facility even though the physician does not have staff privileges at the facility;

(ii) For those patients who have no physician, obtaining the voluntary agreement of physicians with staff privileges at the facility to accept referrals of such patients, perhaps on a rotating basis;

(iii) If an insufficient number of physicians with staff privileges agree to participate in a referral arrangement, requiring acceptance of referrals as a condition to obtaining or renewing staff privileges;

(iv) Establishing a hospital-based primary care clinic through which patients needing hospitalization may be admitted; or

(v) Hiring or contracting with qualified physicians to treat patients who do not have private physicians.

(2) A facility, as required, is a qualified provider under the title XIX medicaid program, but few or none of the physicians with staff privileges at the facility or in a particular department or sub-department of the facility will treat medicaid patients. If the effect is that some medicaid patients are excluded from the facility or from any service provided in the facility, the facility is not in compliance with its community service assurance. To be in compliance a facility does not have to require all of its staff physicians to accept medicaid. However, it must take steps to ensure that medicaid beneficiaries have full access to all of its available services. Examples of steps that may be taken include:

(i) Obtaining the voluntary agreement of a reasonable number of physicians with staff privileges at the facility and in each department or sub-department to accept referral of medicaid patients, perhaps on a rotating basis;

(ii) If an insufficient number of physicians with staff privileges agree to participate in a referral arrangement, requiring acceptance of referrals as a condition to obtaining or renewing staff privileges;

(iii) Establishing a clinic through which medicaid beneficiaries needing hospitalization may be admitted; or

(iv) Hiring or contracting with physicians to treat medicaid patients.

(3) A facility requires advance deposits (pre-admission or pre-service deposits) before admitting or serving patients. If the effect of this practice is that some persons are denied admission or service or face substantial delays in gaining admission or service solely because they do not have the necessary cash on hand, this would constitute a violation of the community service assurance. While the facility is not required to forego the use of a deposit policy in all situations, it is required to make alternative arrangements to ensure that persons who probably can pay for the services are not denied them simply because they do not have the available cash at the time services are requested. For example, many employed persons and persons with other

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collateral do not have savings, but can pay hospital bills on an installment basis, or can pay a small deposit. Such persons may not be excluded from admission or denied services because of their inability to pay a deposit.

§ 124.604 Posted notice.

(a) The facility shall post notices, which the Secretary supplies in English and Spanish, in appropriate areas of the facility, including but not limited to the admissions area, the business office and the emergency room.

(b) If in the service area of the facility the "usual language of households" of ten percent or more of the population, according to the most recent figures published by the Bureau of the Census, is other than English or Spanish, the facility shall translate the notice into that language and post the translated notice on signs substantially similar in size and legibility to, and posted with, those supplied under paragraph (a) of this section.

(c) The facility shall make reasonable efforts to communicate the contents of the posted notice to persons who it has reason to believe cannot read the notice.

§ 124.605 Reporting and record maintenance requirements.

(a) *Reporting requirements*—(1) *Timing of reports*.(i) A facility shall submit to the Secretary a report to assist the Secretary in determining compliance with this subpart once every three fiscal years, on a schedule to be prescribed by the Secretary. The report required by this section shall be submitted not later than 90 days after the end of the fiscal year, unless a longer period is approved by the Secretary for good cause shown.

(ii) A facility shall also submit the required report whenever the Secretary determines, and so notifies the facility in writing, that a report is needed for proper administration of the program. In this situation the facility shall submit the report specified in this section for the filing of reports, within 90 days after receiving notice from the Secretary, or within 90 days after the close of the fiscal year, whichever is later.

(2) *Content of report*. The report must be submitted on a form prescribed by the Secretary and must include information that the Secretary prescribes to permit a determination of whether a facility has met its obligations under this subpart.

(3) The facility shall provide a copy of any report to the HSA for the area when submitting it to the Secretary.

(4) *Institution of suit*. Not later than 10 days after being served with a summons or complaint, the applicant shall notify the Regional Health Administrator for the Region of HHS in which it is located of any legal action brought against it alleging that it has failed to comply with the requirements of this subpart.¹

(b) *Record maintenance requirements*. (1) A facility shall maintain, make available for public inspection consistent with personal privacy, and provide to the Secretary on request, any records necessary to document its compliance requirements of this subpart in any fiscal year, including documents from which information required to be reported under paragraph (a) of this section was obtained. A facility shall maintain these records until 180 days following the close of the Secretary's investigation under § 124.606(a).

§ 124.606 Investigation and enforcement.

(a) *Investigations*. (1) The Secretary periodically investigates the compliance of facilities with the requirements of this subpart, and investigates complaints.

(2)(i) A complaint is filed with the Secretary on the date on which the following information is received in the Office of the Regional Health Administrator for the Region of HHS in which the facility is located:

(A) The name and address of the person making the complaint or on whose behalf the complaint is made;

(B) The name and location of the facility;

(C) The date or approximate date on which the event complained of occurred, and

¹The addresses of the Regional Office of HHS are set out in 45 CFR 5.31.

(D) A statement of what actions the complainant considers to violate the requirements of this subpart.

(ii) The Secretary promptly provides a copy of the complaint to each facility named in the complaint.

(3) When the Secretary investigates a facility, the facility shall provide to the Secretary on request any documents, records and other information concerning its operations that relate to the requirements of this subpart.

(4) The Act provides that if the Secretary dismisses a complaint or the Attorney General has not brought an action for compliance within six months from the date on which the complaint is filed, the person filing it may bring a private action to effectuate compliance with the assurance. If the Secretary determines that he will be unable to issue a decision on a complaint or otherwise take appropriate action within the six month period, he may, based on priorities for the disposition of complaints that are established to promote the most effective use of enforcement resources, or on the request of the complainant, dismiss the complaint without a finding as to compliance prior to the end of the six month period, but no earlier than 45 days after the complaint is filed.

(b) *Enforcement.* (1) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility did not comply with the requirements of this subpart, he may take any action authorized by law to secure compliance, including but not limited to voluntary agreement or a request to the Attorney General to bring an action against the facility for specific performance.

(2) If the Secretary finds, based on his investigation under paragraph (a) of this section, that a facility has limited the availability of its services in a manner proscribed by this subpart, he may, in addition to any other action that he is authorized to take in accordance with the Act, require the facility to establish an effective affirmative action plan that in his judgment is designed to insure that its services are made available in accordance with the requirements of this subpart.

§ 124.607 Agreements with State agencies.

(a) Where the Secretary finds that it will promote the purposes of this subpart, and the State agency is able and willing to do so, he may enter into an agreement with the State agency for the State agency to assist him in administering this subpart in the State.

(b) Under an agreement, the State agency will provide the Secretary with any assistance he requests in any one or more of the following areas, as set out in the agreement:

(1) Investigation of complaints of noncompliance;

(2) Monitoring the compliance of facilities with the requirements of this subpart;

(3) Review of affirmative action plans submitted under § 124.606(b);

(4) Review of reports submitted under § 124.605;

(5) Making initial decisions for the Secretary with respect to compliance, subject to appeal by any party to the Secretary or review by the Secretary on his own initiative; and

(6) Application of any sanctions available to it under State law (such as license revocation or termination of State assistance) against facilities determined to be out of compliance with the requirements of this subpart.

(c) A State agency may use funds received under section 1525 of the Act to pay for expenses incurred in the course of carrying out this agreement.

(d) Nothing in this subpart precludes any State from taking any action authorized by State law regarding the provision of services by any facility in the State as long as the action taken does not prevent the Secretary from enforcing the requirements of this subpart.

**APPENDIX TO SUBPART G OF PART 124—
INTERIM PROCEDURES AND CRITERIA
FOR REVIEW BY HEALTH SYSTEMS
AGENCIES OF APPLICATIONS UNDER
SECTION 1625 OF THE PUBLIC HEALTH
SERVICE ACT**

In performing reviews under section 1513 (e) of the Public Health Service Act (42 U.S.C. 3001-2(c)) of applications for grants under section 1625 of the Act, health systems agencies shall use the procedures and criteria stated below. A health systems agency

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may not conduct such reviews until the procedures and criteria to be used in conducting the reviews have been adopted by the agency and published in newspapers of general circulation within the health service area or other public information channels.

PROCEDURES

The procedures adopted and utilized by a health systems agency for conducting reviews of applications for grants under section 1625 of the Act shall include at least the following: 1. Except as provided below, notification of the beginning of a review within seven days of the receipt by the health systems agency of the application. Where the application was received by the health systems agency prior to publication of this subpart in the *FEDERAL REGISTER*, notification must be made within seven days of the date on which the health systems agency adopts its procedures and criteria. The notification shall include the proposed schedule for the review, the period within which a public hearing during the course of the review may be requested (which must be a reasonable period from the transmittal of the written notification required above), and the manner in which notification will be provided of the time and place of any hearings so requested. Written notification to members of the public may be provided through newspapers of general circulation in the area and public information channels. Notification to the applicant whose application is being reviewed and all other applicants for assistance under section 1625 of the Act providing health service in the health service area shall be by mail (which may be as part of a newsletter). The health systems agency must simultaneously notify the Federal funding agency of the beginning of the review.

2. Schedules for reviews which provide that such reviews shall not exceed 60 days from the date of notification made in accordance with paragraph 1 of this section to the date of the written findings made in accordance with paragraph 4 of this section. This does not preclude a health systems agency from conducting its review in less than 60 days.

3. Provision for applicants to submit to the health systems agency (in such form and manner as the agency shall require) such information as the agency deems necessary in order to conduct its review.

4. Written findings which state the basis for the approval or disapproval of the application by the health systems agency. Such findings shall be sent to the applicant, the State health planning and development agency (or agencies), and the Secretary, and shall be available to other upon request.

5. Access by the general public to all such applications reviewed by the health systems agency and to all other written materials pertinent to the agency review.

6. Public hearings in the course of agency review, if requested by one or more persons directly affected by the review. For purposes of this paragraph, a "person directly affected by the review" is as defined in 42 CFR 122.306 (a)(7).

CRITERIA

The specific criteria adopted and utilized by a health systems of this agency to conduct reviews of applications for grants under section 1625 of the Act shall include at least the following:

1. The relationship of the health services of the facility to the applicable health systems plan and annual implementation plan.

2. The relationship of the health services of the facility to the long-range development plan (if any) of the applicant.

3. The need that the population served or to be served by the facility has for the health services of such facility.

4. The availability of alternative, less costly, or more effective methods of providing the health services which the facility provides.

5. The relationship of the health services provided by the facility to the existing health care system of the area.

6. The availability of resources (including health manpower, management personnel, and funds for capital and operating needs) for the provision of services by the facility and the availability of alternative uses of such resources for the provision of other health services.

7. The special needs and circumstances of those entities which provide a substantial portion of their services or resources, or both, to individuals not residing in the health service area in which the entities are located or in adjacent health service areas. Such entities may include medical and other health professions schools, multidisciplinary clinics, and other speciality centers.

8. The special needs and circumstances of health maintenance organizations for which assistance may be provided under title XIII.

9. The costs and methods of the proposed construction or modernization, including the costs and methods of energy provision.

10. The probable impact of the project reviewed on the applicant's costs of providing health services.

Subpart H—Recovery of Grant Funds

AUTHORITY: Secs. 609 and 1622 of the Public Health Service Act as amended 98 Stat. 112 (42 U.S.C. 291i and 300s-1a).

SOURCE: 51 FR 7939, Mar. 7, 1986, unless otherwise noted.

Public Health Service, HHS**§ 124.704****§ 124.701 Applicability.**

The provisions of this subpart apply to facilities with respect to which grant funds were paid for construction or modernization—

- (a) Under title VI or XVI of the Public Health Service Act; or
- (b) Pursuant to the authority of the Secretary under any of the following statutes:
 - (1) The Public Works Acceleration Act of 1962, Pub. L. 87-658 (42 U.S.C. 2641 *et seq.*);
 - (2) The District of Columbia Medical Facilities Construction Act of 1968, 82 Stat. 631 (Pub. L. 90-457);
 - (3) The Appalachian Regional Development Act of 1965, as amended (40 U.S.C. App.).

§ 124.702 Definitions.

As used in this subpart—

Act means the Public Health Service Act.

Department means the Department of Health and Human Services.

Expected useful life means the period of time during which the structure may reasonably be expected to perform the function for which it was designed or intended.

Facility means a facility with respect to which grant funds were paid under any of the authorizations listed in § 124.701.

Fiscal year means the facility's fiscal year.

Nonprofit, as applied to any facility, means a facility that is owned and operated by one or more nonprofit corporations or associations no part of the net earnings of which inures, or may lawfully inure, to the benefit of any private shareholder or individual.

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

State agency means (1) in the case of a facility with respect to which a grant was made under title VI of the Public Health Service Act or any of the statutes listed in § 124.701(b), the State agency designated pursuant to section 604 of the Public Health Service Act or its successor agency, and (2) in the case of a facility with respect to which a

grant was made under title XVI of the Public Health Service Act, the State health planning and development agency designated pursuant to title XV of the Public Health Service Act.

Then value means the value of the facility on the date the facility is sold, transferred or ceases to be used for a permissible use as described in § 124.704.

§ 124.703 Federal right of recovery.

(a) If any facility is at any time within 20 years after the completion of the grant-assisted construction or modernization sold or transferred to any entity which is either not qualified for a grant under the statute pursuant to which the grant was awarded or not approved as a transferee by the State agency, the United States shall be entitled to recover on the basis of joint and several liability from any transferor, transferee, or successive transferee of the facility an amount determined in accordance with this subpart.

(b) If any facility at any time within 20 years after the completion of the grant-assisted construction or modernization ceases to be a public or other non-profit facility that would have been eligible for a grant under the statute pursuant to which the grant was awarded, the United States shall be entitled to recover from the owners of the facility an amount determined in accordance with this subpart.

§ 124.704 Notification of sale, transfer, or change of use.

(a) The transferor of a facility that is sold or transferred as described in § 124.703(a), or the owner of a facility which ceases to be a public or other nonprofit facility as described in § 124.703(b), shall provide the Secretary written notice of such sale, transfer, or other change not later than 10 days after the date on which the sale, transfer, or change occurs.

(1) *Transfer*. For purposes of this subpart, a transfer occurs when a facility is conveyed to another entity through lease, merger, bankruptcy, foreclosure, or other arrangement.

(2) *Cease to be*. For purposes of this subpart,

(i) A facility "ceases to be" a facility for which a grant could have been made under the statute pursuant to which

§ 124.705

the grant was awarded when it is no longer operated as such a facility; and

(ii) A facility “ceases to be a public or nonprofit facility” when an entity that is not a public or other non-profit corporation or association assumes management responsibilities with respect to the facility which, in the Secretary’s judgment, are so pervasive as to constitute operation of the facility. The manager will not be deemed to be the operator of the facility if the management agreement contains both of the following provisions:

The Board of Directors of the facility retains authority to terminate the agreement at any time upon reasonable notice to the contractor.

No employee of the contractor may be a member of the facility’s Board of Directors.

In the absence of either of these provisions the Secretary will consider the degree of control granted to the managing organization over patient admission, determination of what services will be provided, and charges for services provided in the facility.

(b) *Content of Notice.* The notice required by paragraph (a) of this section shall be sent to the Secretary by certified mail, and shall contain or be accompanied by

(1) The date of the sale, transfer, or other event that gives rise to the notice;

(2) Copies of any sales contracts, lease agreements, management contracts or other documents pertinent to the event giving rise to the notice;

(3) Estimates of current assets, current liabilities, book value of equipment, the expected value of land on the new owner’s books, and the remaining depreciation for all fixed assets involved in the transaction calculated on a straight line basis using commonly adopted expected useful lifetimes.

(c) *Failure to provide notice.* Failure to provide the information required by paragraph (b) of this section, will be considered failure to provide the notice required by this section. In any case in which such information has not been provided, the Secretary will, promptly upon receiving an incomplete notice or otherwise discovering that a sale, transfer or other event giving rise to a recovery may have occurred, send a letter to the owner of the facility re-

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questing the information needed to calculate a recovery amount.

(Approved by the Office of Management and Budget under control number 0915-0099)

§ 124.705 Amount of recovery.

(a) Except as provided in § 124.706, the amount that the United States shall be entitled to recover under this subpart is that amount bearing the same ratio to the then value of so much of the facility as constituted an approved project (or projects) as the amount of Federal participation bore to the cost of the construction or modernization under such project (or projects).

(b) The then value of the facility will be based on:

(1) The transaction value in the case of an arms-length sale or transfer, or

(2) A depreciated reproduction value in the absence of an arms-length sale or transfer or if the buyer fails to provide, within 60 days after the date of the Secretary’s letter described in § 124.704(c), the information which, in the judgment of the Secretary, is necessary to establish, adjust, and apportion a transaction value. As used in this section, “transaction value” means in the case of a sale, the sale price, and in the case of a lease, the value of the lease plus the residual value of the facility at the termination of the lease (i.e., the reproduction value or, if appropriate, an alternative use value).

(c) The transaction value will be adjusted to account for the purchase or lease of other assets and the assumption of liabilities associated with the transaction. To determine the amount of Federal recovery, the adjusted value will be apportioned to the grant-aided assets by the ratio of the remaining useful lifetime values of those assets to the sum of the remaining useful lifetime values of all assets not previously accounted for in adjusting the transaction value.

(d) A depreciated reproduction value will be established by calculating a reproduction value using construction cost indexes or current costs per square foot for construction, depending on which is more relevant to the type of construction associated with the grant. This reproduction value will then be adjusted by the ratio of the remaining

useful life to the total useful life for the assets involved.

(e) In calculating the recovery amount, the Secretary will include as Federal participation any grant assistance received by the facility under an authority listed in § 124.701 and any assistance supplementary to that assistance received for the construction or modernization of the facility under the Public Works and Economic Development Act of 1965 (42 U.S.C. 3121, *et seq.*) or the Local Public Works Capital Development Act of 1976 (Pub. L. 94-369).

§ 124.706 Calculation of interest.

(a) In addition to the amount of recovery calculated under § 124.705, the United States shall be entitled to recover interest on such amount in accordance with this section at the rate determined by the Secretary based on the average of the bond equivalent of the weekly ninety-day U.S. Treasury bill auction rate for the quarter previous to the quarter in which interest begins to accrue under this section.

(1) *Change of status before July 18, 1984.* For facilities that were sold or transferred or which ceased to be public or other nonprofit facilities before July 18, 1984, interest will be charged beginning August 17, 1984, or 180 days after the date of such sale, transfer or other, whichever is later, and ending on the date the amount the United States is entitled to recover is collected.

(2) *Change of status after July 17, 1984.* For facilities that are sold or transferred or which cease to be public or other nonprofit facilities after July 17, 1984, interest will be charged beginning 180 days after receipt by the Department of the notice required under § 124.704; *Provided*, That if such notice is not provided as prescribed, interest will be charged beginning on the date of the sale, transfer, or change of use, and ending on the date the amount which the United States is entitled to recover is collected.

(b) The Secretary may waive interest charges that result from delays caused solely by the Department.

§ 124.707 Waiver of recovery where facility is sold or transferred to a proprietary entity.

(a) *Conditions of the waiver.* The Secretary may waive the recovery rights of the United States arising under § 124.703(a) if the entity to which the facility was sold or transferred:

(1) Has filed a written request for the waiver within the time limits prescribed by this section;

(2) Has established an irrevocable trust in accordance with this section, in an amount equal to the greater of the amount that would otherwise have been recovered pursuant to § 124.705 (including accrued interest as calculated under § 124.706) or twice the cost of the remaining uncompensated services obligation of the facility as of the date of the change of status, that will be used by the entity only to provide services to those unable to pay in accordance with the requirements of subpart F of this part; and

(3) Has agreed to comply with the community service regulations set out in subpart G of this part.

(b) *Procedures for obtaining waiver.* (1) Within 30 days after the date of receipt of the information described in § 124.704(b), the Secretary will send a letter to the new owner of the facility advising of the United States' right of recovery and the opportunity to obtain a waiver. For the purpose of advising the new owner of the amount to be placed in the irrevocable trust should the owner wish to obtain a waiver, the letter will also state the dollar amount of the remaining uncompensated care obligation and the amount that would be due under § 124.705, computed as follows:

(i) *Computation of uncompensated care obligation.* (A) For a facility which changes status before the date that subpart F of this part is effective for the facility, the remaining uncompensated services obligation is zero.

(B) For a facility which changes status after the date that subpart F of this part is effective for the facility, the Secretary will multiply the annual compliance level, computed under the 10% method specified in 42 CFR 124.503(a)(1)(ii), for the fiscal year in which the change of status occurs times the number of years remaining

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in the facility's uncompensated services obligation. From this amount, the Secretary will subtract amounts of excess or add amounts of deficit for each fiscal year prior to the change of status for which the Secretary has previously conducted an audit of uncompensated services accounts. Excess and deficits will be adjusted by the percent change in the National Consumer Price Index for Medical Care between the year in which the excess or deficit occurred and the year in which the status change occurred. For each fiscal year prior to the change of status which the Secretary has not audited, the Secretary will add to the remaining obligation an amount equal to the annual compliance level in each such year adjusted by the percent change in the National Consumer Price Index for Medical Care between that year and the year of the status change. The amount computed as the total remaining obligation will then be multiplied by two. If the transferee chooses to accept the Secretary's calculation, no further assessments will be made of uncompensated care provided prior to the change of status date. If the transferee does not accept the calculation, the transferor or transferee may hire, and may charge against the irrevocable trust established under this section, an independent auditor to certify the compliance level and any excess or deficit for the period from May 18, 1979, up to and including the date of the change of status, using standard Departmental procedures supplemented with instructions provided by the Secretary, and submit the results in accordance with paragraph (b)(2)(ii) of this section. The audit may be conducted for any years not included in a previous site assessment conducted by the Department. If the Secretary agrees that a change is appropriate, the Secretary will use this information to adjust the calculation as set out in paragraph (b)(3) of this section. If the independent auditor certifies that qualified care was rendered either at the facility or at a replacement facility operated by the transferee between the date of the change of status and the date of establishment of the trust, and the Secretary agrees, the post transfer level of care shall not affect the calculation of the total re-

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maining uncompensated care obligation to be doubled, but instead shall be recognized as a credit to be drawn from the trust as provided in paragraph (c)(1)(ii) of this section. In the case of a facility with respect to which a grant was made under title XVI of the Act, the remaining period of obligation will be the remainder of the expected useful life of the facility, as follows: 40 years for buildings, 30 years for additions, 20 years for building renovations, 20 years for fixed equipment and 12 years for major movable equipment.

(ii) *Computation of recovery amount.* The Secretary will determine the recovery amount as provided in § 124.705.

(2) Within 60 days following the date of the Secretary's letter provided pursuant to paragraph (b)(1) of this section, the owner of the facility shall notify the Secretary in writing that it either:

(i) Accepts the trust fund amount for the waiver as offered by the Secretary;

(ii) Provides a detailed statement of an alternative determination of the recovery amount or an independent audit of the remaining uncompensated services obligation as described in paragraph (b)(1)(i) of this section; or

(iii) Does not seek a waiver under § 124.707. Failure to provide a timely response to the Secretary under this subparagraph will be considered an election not to seek the waiver.

(3) Within 30 days following the receipt of the owner's views concerning the calculation, and after considering those views, the Secretary will send a final letter providing the Secretary's determination of twice the remaining uncompensated care obligation and the recovery amount under § 124.705. The amount to be placed in the irrevocable trust will be the higher of those two figures. (See paragraph (a)(2) of this section.)

(4) Within 30 days of the date of the final letter, the owner of the facility shall notify the Secretary in writing whether or not it accepts the terms of the waiver. Failure to provide timely notice to the Secretary under this subparagraph will be considered an election not to accept the waiver.

(c) *Establishment of the trust.* (1) Within 60 days of the date of its acceptance of a waiver under paragraph (b)(2) or

(b)(4) of this section, the owner shall begin delivering services to those unable to pay in accordance with subpart F of this part under an irrevocable trust established in the amount calculated pursuant to paragraph (b) of this section. *Provided*, That

(i) The owner shall provide a copy of the trust documents to the Secretary and no trust shall be considered established until the trust documents have been approved by the Secretary; and

(ii) The owner may credit against the trust any uncompensated services provided in accordance with subpart F of this part between the date of the change of status of the facility and the establishment of the trust. For an owner to receive the credit before the establishment of the trust and deposit of funds therein, the auditor's report covering the post-transfer period shall be submitted with the notification of acceptance of the waiver, and in any event, not later than 30 days from the date of the Secretary's final letter described in paragraph (b)(3) of this section. Within 30 days following the receipt of the auditor's report, the Secretary will notify the owner of the allowable credit, if any. If the auditor's report is not timely submitted, the trust must be established and fully funded, in accordance with the time limits imposed by paragraph (c)(1) of this section, and the Secretary will notify the owner of the allowable credit, if any, within 30 days of the date of the establishment of the trust or within 30 days of the receipt of the report, whichever is later.

(2) The trust shall be administered by a Trustee who is neither an employee of the transferee nor an employee of a subsidiary or of the parent institution of the transferee.

(3) The trust shall provide that the trust corpus and income may be invested only in U.S. Government or U.S. Government insured securities.

(d) *Use of the trust.* The corpus and income of the irrevocable trust shall be used to pay for the costs of uncompensated services, which may include reasonable costs of establishing and administering the trust and the cost of the independent audit described in

paragraph (b)(1)(i) of this section, until the trust is exhausted.

(Approved by the Office of Management and Budget under control number 0915-0099)

§ 124.708 Waiver of recovery—good cause for other use of facility.

The Secretary may for good cause waive the recovery rights of the United States arising under § 124.703(b). In determining whether there is good cause under this section for releasing the applicant or other owner of the facility from its obligation, the Secretary will take into consideration the extent to which:

(a) The facility will be devoted by the applicant or other owner to use for another public or nonprofit purpose which will promote the purpose of the Act;

(b) There are reasonable assurances that for the remainder of the 20-year period other public or nonprofit facilities not previously utilized for the purpose for which the facility was constructed will be so utilized and are substantially equivalent in nature and purpose.

(c) The facility has been acquired from an agency of the United States (e.g., the Federal Housing Administration under its mortgage insurance commitment program) which has made a reasonable effort to dispose of it for operation as a public or nonprofit health care facility.

[51 FR 7939, Mar. 7, 1986, as amended at 57 FR 8272, Mar. 9, 1992]

§ 124.709 Withdrawal of waiver.

(a) Any waiver granted under this subpart is conditioned upon the recipient of the waiver carrying out the obligations imposed by § 124.707 or § 124.708 as applicable.

(b) The Secretary will monitor compliance with the community service and uncompensated care obligations of any entity that receives a waiver.

(c) Should a recipient of a waiver fail to comply with the applicable conditions, the Secretary will withdraw the waiver and seek recovery based on the value of the facility on the date the right of recovery first arose under § 124.703.

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(d) No waiver will be withdrawn until the recipient has been notified in writing by the Secretary of the noncompliance and has failed to take corrective action within 90 days after the date of such notice.

(e) Should the waiver be withdrawn, the amount of the Government's recov-

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ery will be the amount set out in the Secretary's determination letter as described in § 124.707 (b)(1) or (b)(3) as applicable plus interest from the date of the notification sent in accordance with paragraph (d) of this section.

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