# TAB B

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# Department of Health and Human Services

Public Health Service

42 CFR Part 124
Medical Facility Construction and Modernization; Requirements for Provision of Services to Persons Unable To Pay; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Public Health Service**

**42 CFR Part 124**

## Medical Facility Construction and Modernization; Requirements for Provision of Services to Persons Unable To Pay

[Editorial Note: This reprint incorporates corrections published in the Federal Register of Monday, December 21, 1987.]

**AGENCY:** Public Health Service, HHS.

**ACTION:** Final rule.

**SUMMARY:** The final rule below amends the existing regulations governing how certain public and private nonprofit health care facilities assisted under Titles VI and XVI of the Public Health Service (PHS) Act may fulfill the assurance, given in their application for assistance, that they would provide a reasonable volume of services to persons unable to pay. This final rule enhances the interest of the intended beneficiaries of the assurance by: (1) Increasing facility incentives for compliance by reducing administrative burdens; and (2) permitting facilities to receive credit for substantial compliance, thus enabling the Department to focus its enforcement resources on facilities which are not in substantial compliance.

**DATE:** These regulations are effective February 1, 1988, except for §§ 124.509(c), 124.514(c), 124.515(b)(2)(ii), and 124.515(b)(3)(ii)(B). For additional information concerning this effective date, see the discussion of the Information Collection Requirements below.

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**SUPPLEMENTARY INFORMATION:** On August 29, 1986, the Secretary of Health and Human Services proposed amendments to the rules governing what is popularly known as the Hill-Burton Uncompensated Services Program. 51 FR 31000. Health care facilities covered by the program received construction assistance under two titles of the PHS Act—Title VI (the "Hill-Burton Act," 42 U.S.C. 291, *et seq.*) and Title XVI (42 U.S.C. 300q, *et seq.*). As a condition of such assistance, facilities assisted under Title VI were required to give what is now known as the "uncompensated services" assurance. Under section 603(e) of the Act (42 U.S.C. 291c(e)), the Secretary was authorized to issue regulations requiring assurance that—

> there will be available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor, but an exception shall be made if such a requirement is not feasible from a financial viewpoint.[1]

Regulations requiring the assurance were issued shortly after enactment of Title VI in 1946. *See,* 12 FR 6176 (September 16, 1947). This initial regulatory standard for compliance with the assurance was general. Beginning in 1972, however, a series of regulatory and statutory developments occurred which culminated in the detailed requirements of the present regulations, which were issued in 1979. The objective of the amendments below is to simplify and increase the flexibility of the regulations, while increasing the incentives for compliance. Because the significance of the amendments can be understood only in the context of the requirements of the 1979 regulations, the pertinent sections of the 1979 regulations are summarized below, followed by a discussion of the public comments on the proposed rule and the Department's response thereto.

### I. Summary of the 1979 Regulations

Following extensive public comment, in 1979 the Secretary issued the rules which are codified at 42 CFR Part 124, Subpart F. 44 FR 29372 (May 18, 1979). These regulations established a fixed dollar annual compliance standard—the lesser of 3% of the facility's operating costs (less Medicare and Medicaid reimbursement) or 10% of the Federal financial assistance it received. 42 CFR 124.503(a). A facility that did not meet its annual quota was required to make up the deficit in the amount of uncompensated services provided in later years. 42 CFR 124.503(b). In addition, the facility was required to institute an affirmative action plan designed to prevent recurrence of the deficit. 42 CFR 124.504. A facility could also get credit for "excess"—that is, uncompensated services provided over and above its annual quota—and credit that excess against its quota in a future year. 42 CFR 124.503(c). The 10% compliance level, and the deficits and excesses, were required to be adjusted by a factor that reflects inflation, the so-called "inflation factor." 42 CFR 124.503(d). In each case, however, the facility could only count a portion of the cost of the service provided toward the quota, the so-called "allowable credit." 42 CFR 124.502. Facilities were required to exclude third party payments (including payments from Medicare and Medicaid) from the quota, and also could not count towards the quota the differential between the amount of third party reimbursement and allowable credit where required by the third party program to accept the reimbursement as payment in full for service. In addition, the regulations provided that services disallowed as unnecessary by a Professional Standards Review Organization (PSRO) must also be excluded. 42 CFR 124.509.

The 1979 regulations established national eligibility criteria, based on the poverty income guidelines presently issued by the Department. 42 CFR 124.506. The criteria considered only income, not assets, and a mandatory procedure for calculating income was provided. *Id.* Facilities were given limited discretion to decide how to allocate their quota of uncompensated services among eligible persons. 42 CFR 124.507. Facilities could credit services toward their quota only if they made an eligibility determination within two working days of a request for uncompensated services and met certain other requirements. 42 CFR 124.508.

The 1979 regulations contained explicit requirements for notice, including that written notice be given to each person seeking service in the facility. 42 CFR 124.505(d). In addition, facilities were required to publish and post notices and under certain circumstances to provide notice to the local health systems agency (HSA). 42 CFR 124.505. The regulations contained a number of reporting and recordkeeping requirements. 42 CFR 124.510.

On September 18, 1986, the Department issued final rules amending Subpart F to establish a compliance alternative for certain publicly-owned facilities. 51 FR 33208. The provisions of the September 18, 1986, rule have been incorporated, with a few minor editorial changes, in the rules below.

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[1] The assurance required by statute of title XVI assisted facilities, of which there are only 38, was as follows:

> * * * reasonable assurance that at all times after such application (for Title XVI assistance) is approved * * * (ii) there will be made available in the facility or portion thereof to be constructed, modernized or converted a reasonable volume of services to persons unable to pay therefor and the Secretary, in determining the reasonableness of the volume of services provided, shall take into consideration the extent to which compliance is feasible from a financial viewpoint.

Section 1621(b)(1)(K), 42 U.S.C. 300s-1 (b)(1)(K), as redesignated by Pub. L. 96-79.

## II. Background and Summary of Public Comments and Policies of the Final Rule

### A. Proposed Rule

The basic objective of the 1979 regulations was to assure that recipients of Titles VI and XVI funds who gave the uncompensated services assurance provide services free or below cost to persons who cannot afford to pay for them within the context of sound planning for and management of the delivery of health care services. The proposed rules retained the basic policies of the 1979 rules, but refined some provisions in order to lessen the administrative burden of compliance for facilities, while increasing the incentive for compliance by facilities in order to protect the interests of the intended beneficiaries of the assurance. The proposed rules thus sought to establish balance among the basic principles inherent in the proper operation of an uncompensated services program: (1) The provision of a "reasonable volume" of free or below cost health services to eligible persons; (2) the provision of reasonable and equal opportunity to such persons to apply for and receive those services; and (3) the documentation by facilities that a "reasonable volume" of services and opportunity to apply were provided.

Th 1979 regulations relied on strict adherence to the procedural requirements to establish whether or not each patient's uncompensated services account is creditable toward a facility's obligation. They provided no basis for obtaining credit on other grounds, such as a facility's substantial compliance with the three basic principles above. This skewed the incentive for compliance toward some regulatory requirements and away from others. It also consumed the Department's limited resources in account-by-account audits of individual facilities, lessening its ability to monitor the universe of Hill-Burton facilities for systemic problems of compliance.

The proposed rules addressed this problem by eliminating or relaxing a number of the more technical requirements of the 1979 rule, such as the requirements relating to publication of allocation plans, timing of determinations, timing of deficit make-up, and reporting and recordkeeping. In addition, they departed from the account-based approach of the current rules as the benchmark of compliance. Instead, under the proposed rules, a facility in substantial compliance with the requirements necessary for the proper operation of an uncompensated services program would be given credit for its compliance, while a facility showing a pattern of substantial noncompliance with major substantive provisions of the rule would be subject to receiving no credit for the period in which noncompliance was found. *See*, proposed § 124.511(b)(1) and § 124.512(c). A certification of substantial compliance would be based on procedures determined by the Secretary to be sufficient to establish compliance, including examination of the systems that facilities put in place to comply with the notice, recordkeeping and determination of eligibility requirements, as well as their compliance with the reporting requirements. The proposed rules also restructured and simplified the regulatory language of the 1979 rules in certain respects in order to help achieve compliance by facilities through promoting a better understanding of the regulatory requirements. *See*, for example, proposed § 124.505(a)(1) (relating to eligibility criteria), § 124.507 (a) and (b) (relating to eligibility determinations), §124.503(b) (relating to deficits), and § 124.508 (relating to cessation of uncompensated services).

The proposed rules also proposed a more flexible compliance standard for facilities with small ($10,000 or less) annual compliance obligations and which routinely provide free or below cost services to persons determined by the facility, under a program based on objective criteria, to be unable to pay for them. Facilities that qualify would be eligible for certification by the Secretary, pursuant to which they would be required only to comply with the requirements of the program of discounted services upon which the certification was based, along with ancillary reporting and recordkeeping requirements, as long as the certification was in effect. *See*, proposed § 124.514. In addition, it was proposed to exempt certain federally funded centers that are required by Federal law to provide free and below cost services, from the procedural requirements of the rules. *See* proposed § 124.503(d). Finally, a method of determining credit for facilities whose compliance had not been previously completely assessed prior to the effective date of the new rules was proposed. *See*. proposed § 124.511(b)(1)(ii).

### B. Public Comments and the Department's Responses

The Department received 80 public comments on the proposed rules from health care facilities, legal services organizations, consumer groups, State officials and consumers. About 60% of these supported the proposed rules. The substantive concerns raised in the public comments, and the Department's responses to the comments are set out below.

#### 1. *Qualifying Services*

Proposed § 124.503(a)(2) established criteria, implicit in the 1979 regulations, for services that qualify as uncompensated services. This section elicited no substantive comment. In light of the revisions relating to the standards for substantial compliance and substantial noncompliance, discussed in section 11 below, proposed § 124.503(a)(2) has been deleted as unnecessary. For the same reason, the reference in proposed § 124.502(l)(1) to the determination of the amount of uncompensated services has been deleted. *See*, § 124.511(b) and § 124.512(c).

#### 2. Deficits

The proposed rules made explicit the dichotomy present in the 1979 rules between types of deficits; in the proposed rules, they were termed "justifiable deficits" and "noncompliance deficits". *See*, proposed § 124.503(b)(1). While the proposed rules continued the policy that justifiable deficits could be made up at any time during or immediately following the facility's period of obligation (*see*, proposed § 124.503(b)(2)(i)), they provided that make-up of noncompliance deficits had to begin immediately. However, in contrast to the 1979 rules (which provided that the deficit must be made up in the next year, if the facility is financially able to do so), the proposed rules provided for spreading make-up of the deficit amount over the remaining period of obligation.

The main criticism of this section was that it permitted make-up of deficits to be postponed indefinitely; the commenters argued that the policies of the 1979 rules should be retained, as there is an immediate need for uncompensated services. Several nursing home organizations argued that the proposed rules did nothing to alleviate what they termed the problem of "compounding deficits." A State agency argued that the deficit calculation should be simplified so that a provider could do it, while a public interest group questioned whether failure to read the providers' manual constituted "justifiable" noncompliance.

The Department has revised the affirmative action plan requirement to provide for accelerated make-up where the facility fails to comply with that requirement. *See*, § 124.503(b)(4) below. Otherwise, the final rule remains as proposed. The comments criticizing the

proposed rule as permitting indefinite postponement of the deficit make-up mischaracterize both the 1979 and the proposed rules. The proposed rule was identical to the 1979 rules with respect to justifiable deficits. *Compare,* § 124.503(b)(1) of the 1979 rules and proposed § 124.503(b)(2)(i). Nor does the final rule permit indefinite postponement of deficit make-up; to the contrary, deficit make-up must begin immediately. *See,* § 124.503(b)(2)(ii) below. Under § 124.503(b)(4) below, a facility that incurs a deficit is required to institute an affirmative action plan designed to enable it to meet its annual compliance level which, under § 124.503(b)(3)(iii), includes a portion of the deficit. Thus, the affirmative action plan requirement further promotes the make-up of noncompliance deficits, as does the change to § 124.503(b)(4) providing for the potential for accelerated make-up where there is a failure to comply with the plan requirement. With respect to the remaining comments, the Department believes that the changes elsewhere in the rule should help nursing homes avoid deficits. We disagree with the comment regarding the need to simplify calculation of the deficit make-up, as the calculation of the deficit under § 124.503(b)(3) requires only one additional, simple arithmetic calculation compared to the 1979 rules. Finally, what constitutes a "justifiable deficit" is made clear by § 124.503(b)(1)(i), which also clarifies that a deficit due to failure to follow the applicable procedures is not justifiable.

3. Excesses

The proposed rules proposed a new method for calculating the amount of excess (*i.e.,* uncompensated services in excess of a facility's annual compliance level) a facility needs to "buy out" of its uncompensated services obligation. The buy out formula proposed sought to remedy two anomalies that had become apparent under the buy out formula of the 1979 rules. First, it proposed that a three-year average of a facility's annual compliance levels constitute the basis of the formula, to remedy the problem occasioned by abnormal swings in compliance levels due to unusually large Medicaid or Medicare reimbursements in a particular year. *See,* proposed § 124.503(c)(3)(i). Second, it was proposed to change the formula for recipients of loan assistance to take into account subsidies received after the buy out year. *See,* proposed § 124.503(c)(3)(ii). In addition, it was proposed to require that any claims of excess over 100% of a facility's annual compliance level be substantiated by an independent audit. *See,* proposed § 124.503(c)(4).

The proposed changes to the buy out formula received little comment, with one legal services organization commending it and a hospital criticizing it on the ground that it penalized facilities with multiple grants where the 20-year period of one or more grants had recently expired. The proposed independent audit requirement, however, received extensive comment. In general, facilities claimed that it was an unfair and costly requirement, with no logical basis. Consumer groups, on the other hand, argued that the requirement should be extended to the entire claim of excess, on the ground that facilities usually overstate their excess.

The Department agrees with the comment relating to the multiple grant situation, and has revised the buy out provisions in the Final Rule. It establishes a buy out formula pegged to the number of years remaining under obligation for each grant. *See,* § 124.503(c)(3)(i)(A) below. Further, the buy out section has been reorganized to accommodate this change. The buy out formulas retain the differentiation between grant and loan assistance, as in the proposed rule, but are now limited to the method of calculating the annual compliance level in the buy out year. This linkage is similar to that in the existing rule, except that the buy out formula which is linked to the three percent method in the rule below provides for using a three-year average. *See* § 124.503(c)(3)(ii) below. This provision parallels the proposed rule. The Department has also excepted facilities certified under §§ 124.513, 124.514, and 124.515 from the provisions relating to excess. In the Department's view, an early buy out should be available only under the conditions of the main regulations.

The Department has deleted the proposed requirement for an independent audit for claims of excess. The Department's new assessment approach, described more fully below, will be applied to such claims, which makes the proposed requirement unnecessary. This resolution of the issue also responds to the consumer concern that the entire claim of excess should be audited.

4. Notices

The proposed rules proposed to continue the notice requirements of the 1979 rules with only minor changes. The requirement that health systems agencies (HSAs) be notified was deleted, in light of the phasing out of such agencies in many areas. (Since publication of the proposed rules, Title XV of the PHS Act has in fact been repealed.) The requirement that notice of the facility's allocation plan be published 60 days prior to its fiscal year was modified to require publication at any time before the beginning of the fiscal year. *See,* proposed § 124.504(a). Similarly, proposed § 124.506(c) permitted revision of a facility's allocation plan effective upon publication. Finally, the individual written notice requirement was modified to be consistent with the proposed changes to the eligibility determination requirements. *See,* proposed § 124.504(c)(1)(iv).

A couple of facilities objected to the individual written notice requirement as burdensome, one suggesting that the notice should be distributed only to persons claiming to be no-pay or self-pay. A nursing home argued that it was futile, since their uncompensated services are committed on the first day of the fiscal year. The majority of the comments on the notice provision, however, objected to the elimination of the requirement that facilities publish notice 60 days prior to the beginning of their fiscal year. In general, the commenters argued that this change deprived them of an opportunity to comment, since the plan (and any revisions) was effective upon publication. To remedy this problem, a couple of commenters suggested that the plans have a delayed effective date. Other commenters objected to the proposed rule on the ground that it would require them to search the legal notices section every day, which they claimed was impractical.

The Department agrees that the commenters have raised a valid concern regarding the elimination of the 60-day notice requirement. It has accordingly accepted the suggestion for a delay in effective date as the most reasonable means of accommodating both the consumers groups' need for the opportunity to comment on allocation plans and the facilities' need for flexibility in issuing and revising them. Thus, the publication requirements in § 124.506 have been revised to provide that allocation plans (initial and revised) may not become effective until at least 60 days following publication. *See,* § 124.506 (a)(2), (b)(2) and (c). It should be noted that the publication requirement has been changed slightly ("no earlier than") from the requirement in the 1979 regulations. The purpose of this is to give facilities flexibility to publish more than 60 days in advance of a fiscal year or other date and still have a new plan effective on the date

specified. The Department disagrees that such a requirement imposes an unfair burden on consumer groups to check the newspaper. Such an effect is minimal and in any event does not outweigh facilities' need for flexibility in the publication requirements, which has been demonstrated in many assessments. Moreover, the consumer groups' assertion of increased burden derives from a misunderstanding of the 1979 rules; under the 1979 rules, there is no date certain for publication of the allocation plan, as the present 60-day requirement is simply a minimum.

The Department has not accepted the comments urging restriction of the individual written notice requirements. Restricting provision of the individual written notice to only those persons who declared themselves to be self-pay or no-pay would leave uninformed persons who might later become eligible due to an intervening change in circumstances. Nor does the fact that the notice requirement may be inappropriate for one or a few nursing homes made it inappropriate for the universe of regulated facilities. Thus, the individual written notice provision remains as proposed. *See,* § 124.504(c) below.

5. Eligibility Criteria

The proposed rules proposed to revise the eligibility criteria to clarify that the existence of third party coverage for medical services eliminates eligibility for uncompensated services. *See,* proposed § 124.505(a)(1). This policy is consistent with longstanding practice and the Federal view of the uncompensated services program as a program of "last resort." *See,* for example, the discussion at 44 FR 29394, May 18, 1979. In addition, proposed § 124.505 slightly modified the methods of computing income by requiring the use of income preceding the request for uncompensated services, rather than preceding the determination of eligibility. Proposed § 124.505(a)(2) and proposed § 124.505(b) also updated the current requirements, by referencing the "poverty line" issued by the Department, in accordance with section 683(c)(1) of Pub. L. 97–35. Consistent with the current administrative practice, proposed § 124.505(b) established in the regulations that revisions of the poverty line would be effective 60 days following publication in the **Federal Register.**

These provisions generated only a couple of comments, one favorable and one suggesting that loopholes in the eligibility criteria be closed. The Department has not accepted the latter suggestion, as it is of the view that the reasons supporting the adoption of the eligibility criteria in 1979 remain valid, particularly for monitoring purposes. However, the Department believes that the eligibility criteria should be clarified to make explicit what was implicit in the 1979 and the proposed rules, *i.e.,* that a facility's allocation plan also affects eligibility. This condition is now reflected in § 124.505(a)(3) below. Otherwise, § 124.505 remains as proposed.

6. Allocation Plans

The proposed rules retained the allocation plan requirement of the 1979 rules. Facilities would retain their discretion to determine certain specified elements of the allocation plan, including determining which services to make available as uncompensated services, and whether to offer these services to Category B patients. Proposed § 124.506(b)(2) modified the 1979 rule by providing that a facility would be required to operate under its old allocation plan until it published a revised allocation plan.

Aside from the timing issue, discussed in section 3 above, these changes received no comment. The Department has accordingly retained them essentially as proposed, except for the timing changes and a clarification of the presumptive plan requirement which reflects current practice and the restructuring of the regulations. *See,* § 124.506(b)(2) below.

7. Determinations of Eligibility

Proposed § 124.507 retained the basic policies of the 1979 rules in most respects, but clarified serveral points that have proved confusing. Proposed § 124.507(a) clarified that determinations must be written, while proposed § 124.507(b) clarified that denials are a form of determination and spelled out the requirements for conditional determinations. The major change to the determination requirement was proposed § 124.507(c), relating to the timing of determinations. The proposed rule kept for hospitals and most other facilities the requirement of a two-day determination of eligibility in the case of requests for service made before admission or treatment, but eliminated the two-day requirement in situations where liability for the cost of the services has already been assumed. Thus, proposed § 124.507(c)(2) provided that were the request for uncompensated services is made during or after receipt of services, the determination must be made before the close of the first full billing period following the request. Proposed § 124.507(c) contained parallel provisions for nursing homes; however, it required nursing homes to make determinations of eligibility within 10 working days, but no later than the date of admission for requests made prior to admission.

Proposed § 124.507 elicited numerous comments. Providers generally objected that the two-day requirement of the 1979 rules was unfair and unworkable and advocated even greater relaxation of the timing requirements. Consumer groups, on the other hand, objected to the proposed relaxation of the timing requirements, on various grounds. Some objected that loosening of the requirements was unnecessary, as the existing requirements were not burdensome, with determinations being encompassed in the pre-admission screening process or taking "2–3 minutes." Others were concerned that lengthening the interval in which eligibility determinations could be made would lead to increased collection activity by facilities or would cause poor people to be discharged or to check out of hospitals prematurely. A legal services organization commented that the proposed language relating to denials was an improvement. Commenters on both sides requested clarification of the term "first full billing period." A consumer group also requested that the provision for conditional determinations be changed to provide that conditional determinations must be finalized within two days of when the verifying information is received. With respect to the proposed provisions for nursing homes, a long-term care association supported the proposals. A long-term care provider, however, suggested that 10 days was too short a period in which to receive verification, as Medicaid eligibility is not usually verified in less than 30 days; another pointed out that the requirement that pre-service determinations be made no later than the date of admission might require same or next-day determinations where the request is made just before admission.

The rule below is changed very little from the proposed rule. In response to the requests for clarification of the term "first full billing period," the term has been changed to "first full billing cycle." *See,* § 124.507(c)(2) below. It is our understanding that the latter term reflects general usage and is commonly understood by providers. In any event, it is the intent of this language to preclude collection for the services in question prior to the eligibility determination. In its use of the term "first full billing cycle," the rule recognizes that a bill may be issued where a request for

services is made close to the end of a billing cycle with little opportunity for the facility to stop the billing process. Once a request is made, however, it must be acted upon in a time frame designed to preclude collection activities or any additional billing, *i.e.*, the close of the next billing period. Otherwise, the facility will be out of compliance with § 124.507(c)(2) with respect to that account. Accordingly, these changes respond to the consumer concerns that the change in the determination requirements will lead to a substantial increase in collection activities.

The word "admission" in proposed § 124.507(c)(1)(i) has also been changed to "discharge," to be consistent with longstanding program practice, which regards any request made prior to discharge as pre-service. A parallel change has been made to § 124.507(c)(2) with respect to inpatient hospital services. Sections 124.507(c)(1)(ii) and 124.507(c)(2) continue to peg the timing of determinations to the date of admission for nursing home services as the long-term nature of most admissions would make futile a policy tied to discharge. Finally, in response to the concern raised regarding the timing of nursing home determinations, the words "two days following" have been inserted in § 124.507(c)(1)(ii) below. Otherwise, § 124.507 below remains as proposed.

The Department believes that the balance struck in the rules below is a reasonable accommodation between providers' need for increased flexibility and patients' need for timely determinations prior to service. From a facility standpoint, tying the determination requirement to the facility's billing cycle should mesh with facilities' internal accounting and bookkeeping processes. The Department accordingly rejects the providers' requests for further relaxation of the timing requirements. It also rejects the consumer requests that the two-day requirements of the 1979 rules be retained. The Department's experience in numerous facility assessments has shown that, contrary to the commenters' claims, the two-day requirement has been a major compliance problem for many facilities. In the Department's judgment, these compliance problems typically are due to the incompatibility of the requirement with facilities' usual internal accounting and management requirements, rather than willful refusal to comply with the law. With respect to the concern regarding premature discharges, the change in § 124.507(c)(1)(i) and (2) from "admission" to "discharge" preserves the two-day requirement intact for all requests made during hospitalization. The comment criticizing the timing requirement regarding conditional determinations is likewise rejected. The proposed requirement merely brings forward the requirement of the 1979 rules; since, in our experience, that requirement has not been a major source of complaints or compliance problems, we are retaining it unchanged. Finally, we note that the criticism of the 10-day requirement for long-term care facilities as insufficient to permit verification of third party coverage is misplaced. The proper procedure, where the existence of third party coverage is in question, is to make a conditional determination within the 10-day determination period; the determination should then be finalized when the information about third party coverage is provided to the facility.

8. Cessation of Uncompensated Services

Proposed § 124.508 sets forth the conditions under which a facility may cease providing uncompensated services. The conditions simply made explicit and drew together the same requirements in the 1979 rules. This section received no substantive public comment. It has accordingly been retained essentially as proposed. There is only a minor change reflecting reorganization of a portion of the posted notice requirement. *See*, § 124.508(a)(4). In addition, parallel provisions have been added for facilities certified under § 124.514, to reflect the addition in § 124.514(d) of a compliance level for such facilities. *See*, § 124.508(b).

9. Reporting

The proposed rules proposed elimination of the requirements of the 1979 rules that facilities provide copies of their allocation plans, published notices and reporting forms to the HSAs for their areas. Ancillary reductions in reporting were also proposed in the community and migrant health centers and small facility compliance alternatives.

The changes in the reporting requirements attracted little comment. One public health department remarked that the reporting requirements of the 1979 rules were onerous and sought exemption for public facilities while a private nonprofit facility suggested that reporting would be easier if it were required annually instead of triennially.

Section 124.509 below remains as proposed, except for editorial changes necessary to integrate provisions relating to the public facility compliance alternative, adopted on September 18, 1986, into the general regulation and a change to clarify the reporting obligations of facilities certified under §§ 124.514 and 124.515. *See*, § 124.509(b), (c), and (d). The Department notes that the existence of the public facility compliance alternative responds to the concern of the public health department described above. The Department has not accepted the suggestion that it require reports on an annual, rather than triennial, basis, as it is of the view that for most facilities such a change would increase the burden of compliance.

10. Record Maintenance

The 1979 rules required facilities to retain their uncompensated services records for 180 days following the close of the Secretary's investigation under 42 CFR 124.511(a) (which covered both complaint investigations and assessments). The proposed rules would have modified this requirement to require facilities to retain records for three years following submission of their compliance report or 180 days following the Secretary's certification of compliance or close of the Secretary's investigation, whichever is less. *See*, proposed § 124.510(b). The community and migrant health center provisions likewise represented a major reduction in recordkeeping requirements for such centers.

The proposed modification of the record retention requirements elicited numerous comments. The comments of provider organizations were generally favorable, although one provider urged that the rule be modified to make clear that patient advocates could not see individual patient records, as it is too expensive to delete identifying information. Consumer groups, however, uniformly opposed the proposed changes. They argued that the proposed change would permit facilities to, in some cases, retain records for less than a year. This shortening of the record-retention period would, it was argued, permit facilities to avoid monitoring by legal services organizations and others and erect insurmountable problems of proof where a patient seeks to use the Hill-Burton uncompensated services obligation as an affirmative defense to a collection action. One organization asked whether, where a facility has destroyed its records as permitted by the regulation, the Department would accept its triennial report at face value.

The Department views the consumer concerns as largely misplaced, in that they proceed from a misunderstanding of the 1979 rules, as well as from a misconception of how the record retention requirements well interface with the substantial compliance

approach of the rules below and the increased efficiency in the audit process that it projects. Under the 1979 rules, facilities were permitted to destroy their records relating to an assessment or a complaint 180 days following the close of the assessment or complaint investigation. *See*, the last sentence of § 124.510(b)(1) of the 1979 rules. The rules below modify this provision only slightly to require facilities to maintain their records for the lesser of 180 days following the close of an assessment investigation or three years after submission of the report covering that period required under § 124.509, unless the Secretary asks that the records be retained for a longer period. *See*, § 124.510(a)(2). The rules below delete the reference to a complaint investigation because all records, including those related to a complaint, must be retained in accordance with § 124.510(a)(2).

Based on its new audit methods and the efficiencies it expects to realize under the substantial compliance approach, the Department expects to investigate most facilities within the three-year period, so that the former date should control, not the latter. Thus, for the majority of facilities, the period of time which records are actually required to be kept should decrease substantially. It is true that under this system, as one commenter noted, records will in many cases be required to be retained for less than three years, but this will occur only because there has been an assessment investigation which has been closed by the Secretary. The same result is possible, although less likely, under the 1979 rules. Finally, as noted above, the rule below has been modified to provide that the facility retain its records beyond the three-year period if so requested by the Secretary. This provision has been added in part in response to the consumer concerns described above. Thus, where the Secretary has not assessed a facility within the three-year period or a complaint investigation is pending when the three-year period ends, the Secretary may require the facility to retain the relevant records for an additional period of time. This provision also makes the record retention requirements applicable to general facilities parallel more closely those applicable to facilities certified under the compliance alternatives for public facilities and facilities with small annual obligations. *Compare*, §§ 124.510(a)(2) and 124.510(b) below. For these reasons, the Department is of the view that the changes to the record retention requirements are not inconsistent with the consumer concerns regarding monitoring.

The Department disputes the contention that the new provisions will present problems of proof where a facility has been investigated and subsequently discards its records relating to the investigation. If the denial of uncompensated services at issue relates to a request made during the period which is to be investigated, it must, under current and contemplated procedures, be addressed in the course of the investigation, either by means of corrective action or by a determination that the denial was merited, and the investigation will not be "closed" (for purposes of the 180 day requirement) until appropriate action is taken. If, on the other hand, the request is made for services rendered during the period investigated, but the request itself is made *following* the period investigated, that request must be reviewed in terms of the facility's uncompensated services obligation and program as it exists *at the time of the request*, not as it existed at the time services were provided. To the extent legal services organizations and others have assumed the contrary, such an assumption proceeds from a misinterpretation of the 1979 rules, as well as the proposed rules. The belated requests that are apparently the focus of this consumer concern will thus be unaffected by the changes in the rules below.

The record retention requirements for facilities certified under § 124.514 have been revised to parallel those for facilities certified under § 124.513. *See*, § 124.510(b) below. A new provision has been added to make clear the requirements applicable to facilities certified under § 124.515. *See*, § 124.510(c). The reference to subsection (a) of § 124.511 in the current rules with respect to § 124.513 facilities has been deleted in § 124.510(b) below to reflect the reorganization of § 124.511 in the rules below. Finally, the Department has not accepted the provider suggestion that consumers be prohibited from reviewing individual patient accounts to determine compliance. In the Department's view, the policies of the 1979 rules have worked well in this regard and it does not think a case has been made for change.

11. Substantial Compliance

Under the proposed rules, a facility which substantially complied with the most important requirements of the rules could receive full credit for the uncompensated services it claimed, despite failure to comply in particular cases. Concomitantly, if it systematically failed to comply with one of the crucial regulatory requirements—such as the individual written notice requirement—it was subject to losing credit for the entire year, despite the presence of otherwise creditable accounts. *See*, proposed §§ 124.511(b)(1)(i) and 124.512(c). As noted in the preamble to the proposed rules, these provisions were designed to give facilities a strong incentive to comply with the rules across the board "thereby enhancing the provision of services to persons unable to pay while lessening the burden of compliance for facilities that make a good faith effort to comply." 51 FR 31004.

These provisions of the proposed rule evoked widespread comment, both for and against the proposals. Generally, the providers favored the substantial compliance concept, although several stated that the concept of a total disallowance was grossly unfair. Consumers were uniformly opposed to the concept of substantial compliance. These concerns are described more specifically below.

While facilities and provider groups generally favored relaxing the technical requirements that have occasioned disallowances, they expressed a number of reservations about the "substantial compliance" and "substantial noncompliance" concepts. A number of facilities stated that the concept was too vague. Their concerns about vagueness had two aspects: first, they sought clarification of which provisions of the rules would form the basis for the substantial compliance determination; second, they sought clarification of how many instances of noncompliance would produce a finding of substantial noncompliance. Several facilities suggested that there should be an appeal process for those facilities that receive a total disallowance. One facility asked what the impact of these tests would be on previously unassessed years, while another suggested that facilities that are awaiting assessment not be "penalized" by having the inflation factor applied to any deficits thay have to make up.

Many of the consumer comments expressed concerns similar to those of the facilities. The most common criticism of the substantial compliance concept was that it was too vague. The specific consumer concern was that the standard was so general that it would not permit monitoring by consumer groups; several asked how many violations of the regulations a facility could commit and still be in compliance. A related, very common objection was that compliance cannot be determined without audits of individual accounts. A number of commenters also objected

that the substantial compliance concept violated 42 U.S.C. 300s–6, which requires the Secretary to "investigate and ascertain * * * the extent of compliance" of facilities with their uncompensated services assurance. Several other commenters argued that a compliance standard that is not based on audits of individual accounts violates the nonwaivable reporting requirement of 42 U.S.C. 300s, which requires the periodic submission by facilities of "data and information which reasonably supports * * * (their) compliance with (their) assurances." One consumer organization argued that facilities that are out of compliance with the notice requirements should not be found in substantial compliance, while another asked what recourse patients who were "aberrations" would have. Another commenter argued that the concept of "substantial compliance" was not legal in the Sixth Circuit under *Newsom v. Vanderbilt University*, 653 F. 2d 1100 (6th Cir., 1981). Another consumer group argued that the concept of substantial compliance was illegal, as the government has no record showing that facilities have complied in the past.

The Department has attempted to accommodate many of these concerns in the rules below. It has done this by substantially revising the provisions relating to the standards for substantial compliance and substantial noncompliance. *See*, §§ 124.511(b)(3) and 124.512(c) below. In addition, § 124.511(b) has been revised to make clear what many commenters apparently misunderstood about the proposed rule, that substantial compliance determinations will be based on audits of individual accounts. *See*, § 124.511(b)(2) below.

As set forth below, § 124.511(b)(1)(iii) now provides that the standard for determining whether a facility is in substantial compliance with its assurance is result-oriented: whether the facility provided uncompensated services to eligible persons who had equal opportunity to apply for those services. The specific factors that will be considered in making this determination are three, in descending order of importance: (1) Whether any corrective action previously prescribed has been implemented; (2) whether any violations found can be remedied by corrective action; and (3) whether the facility had in place procedures that complied with the basic components of an uncompensated services program and systematically followed them. If the services are in fact provided to eligible persons at no or a reduced charge, the facility will receive credit for them towards its obligation. Conversely, if the facility fails to remedy prior noncompliance where corrective action is prescribed, it is subject to losing credit for *all* uncompensated services it provided in the period covered by the corrective action. *See*, § 124.512(c)(4).

The purpose of these provisions is to minimize harm, both to eligible persons and to facilities. In the context of the uncompensated services assurance, the issue to be addressed is financial: Who will bear the cost of the medical services that are provided? [2] And, generally speaking, an error in resolving that issue produces harm that can be remedied. For example, where a facility erroneously requests full payment from a person who was eligible for discounted services under its allocation plan, it can remedy that error by ceasing collection on the amount erroneously charged, refunding any erroneous payments, and so on. Similarly, where a facility provides uncompensated services to persons whose care is covered by third party payors and charges those amounts to its uncompensated services obligation, the error can be remedied by reducing the uncompensated services claimed by the amount of the ineligible accounts. In such situations, where a remedy is available and is provided, it is the Department's view that the intent of the statute has been met—uncompensated services have been provided to those who qualify for them—and the facility should receive appropriate credit therefor.

Other failures however, are not so easily remedied, and the regulation treats them differently. The most important of these is where eligible persons do not request uncompensated services because of basic deficiencies in a facility's uncompensated services program, such as failure to provide individual written notice or make determinations. Because such situations do not leave a paper trail, they are inherently impossible to monitor or remedy adequately with respect to the people who were affected by the deficiency. Also, in the Department's view, the individual written notice requirement of § 124.504(c) is the primary vehicle for ensuring that eligible persons are able to seek uncompensated services on a timely and equitable basis, while the requirement that the facility document its determinations ensures that it will make eligibility determinations where requested. Thus, if a facility shows a systematic failure to comply with either the individual written notice requirement of § 124.504(c) with respect to persons eligible under its allocation plan or systematically fails to maintain the documentation required by § 124.510, it is presumed to have routinely denied equal opportunity to request and receive uncompensated services to all eligible persons for the period in question. It is accordingly treated as totally out of compliance with its assurance for the period in question, and receives *no* credit towards its uncompensated services obligation. *See*, § 124.512(c) (1) and (3). While these provisions do not directly remedy the injury to persons who would have sought uncompensated services but for for the deficiencies in the facility's program, they do ensure that the class of persons eligible for such services does not lose them through inappropriate crediting where such basic deficiencies in a facility's uncompensated services program exist. Finally, the regulations provide for total disallowance where a facility fails to report as required by § 124.509. *See*, § 124.512(c)(2). The starting point for any finding of substantial compliance is the facility's claim regarding the amount of uncompensated services provided. If the facility claims no services, in the form of a § 124.509 report, there is no basis for a finding of substantial compliance

Another type of noncompliance may also exist—that is, where the facility has failed to comply with a procedural requirement, but the harm is minimal or difficult to ascertain. One example would be where a facility distributes the individual written notice only to persons within its allocation plan, not to all persons seeking service in the facility as required by § 124.504(c). In such a case, eligible individuals have by definition received uncompensated services equitably, so that no individual remedies (such as refund, cessation of collection actions) are called for. Nonetheless, the regulatory requirements have not been complied with, and there is likely to have been harm to persons who later become eligible through, for example, a change in circumstances. Such cases, as noted above, are intrinsically incapable of identification or, even if identified, subject to questions of causation and evidence, and thus not susceptible to individual remedy. Thus, the regulatory approach is to prescribe remedial action on a prospective basis *(e.g.*, distribute the individual written notice to all persons seeking service in the facility),

[2] Commenters frequently assumed that the uncompensated services assurance raises issues of access to medical care. In the usual case, however, the problem of denial of access is one covered by the community service assurance of 42 U.S.C. 291c(e)(1), not the uncompensated services assurance.

to protect the class of eligible persons served by the facility. If the facility thereafter fails to make the prescribed corrective action, it is subject to having *all* accounts for the period covered by the corrective action disallowed. *See,* § 124.512(c)(4); *see also,* § 124.511(b)(1)(iii)(A). Thus, the approach to situations where the likelihood of harm is either small or difficult to assess is to require prospective compliance, but not to disallow for past noncompliance. This will provide a reasonable remedy to the class of eligible persons served by the facility, while at the same time ensuring that the facility is clearly on notice of what procedures are required. If the facility thereafter fails to implement the prescribed corrective action, the regulations assume that the resultant noncompliance is not due to ignorance or mistake, and that a total disallowance is therefore warranted.

The foregoing discussion makes clear that substantial compliance and noncompliance assessments will be based on audits of facility claims, with respect both to their uncompensated services systems generally and individual accounts. In this regard, the Department has developed and tested an audit method based on this approach and is convinced that the above regulatory approach is workable from an administrative standpoint. Thus, it believes that it can undertake the assessments the regulations call for in a time frame which will assure appropriate feedback to both consumers and facilities. This audit methodology (provided for in § 124.511(b)(1)(ii) below) renders irrelevant the various consumer criticisms of the proposed rule based on the perceived lack of provision for audits of individual accounts.

In the Department's view, the changes above also respond to most of the commenters' other concerns. The basis for a substantial compliance (or noncompliance) determination is principally the availability and implementation of corrective action which, by definition, will be very specific. *See,* § 124.512(b). Not only will the corrective action itself be tailored to the uncompensated services program of the facility in question, but it will be based on the underlying regulatory compliance standards (*e.g.,* §§ 124.505, 124.506, 124.507), which all commenters appear to agree are sufficiently specific. This approach thus responds to the vagueness concerns of both facilities and consumers. More important, the stress on corrective action ensures both groups that a finding of substantial compliance is made only where past noncompliance is appropriately remedied for consumers and that it reflects and appropriately treats such remedial action in terms of a facility's uncompensated services obligation as a whole. The same considerations respond to the consumer concerns with monitoring. The compliance standards remain very similar to those of the 1979 rules, and should present no qualitatively different monitoring problem. What is different under the approach below is the relative availability of a remedy for consumers who believe that they have been denied uncompensated services to which they are entitled. A consumer who can establish an improper denial to the Secretary's satisfaction will now have greater leverage in the administrative process, pursuant to § 124.511(b)(1)(iii)(A). The Department agrees with the consumer argument that facilities that are out of compliance with the notice requirements should not be found in substantial compliance, and the regulations below reflect this. *See, e.g.,* § 124.512(c)(1). With respect to the issue of an appeal for a total disallowance, it notes that an administrative review is available for facilities under current procedures, and there is no plan to eliminate this.

The Department has not accepted the remaining comments regarding the substantial compliance and noncompliance concepts. The Department is not persuaded that the cited holding in the *Newsom* litigation (which it notes appeared in the district court opinion only) is of any relevance to the instant regulations, as the *Newsom* case pertained solely to the regulatory compliance standards issued in 1972. The Department likewise disagrees with the commenter who implied that it lacks the legal authority to adopt a substantial compliance standard absent a showing of past compliance by Hill-Burton facilities. Aside from the factual fallacy underlying this contention, the Secretary's discretion to determine the standards of compliance with the assurance is not limited by the presence (or absence) of past compliance. Finally, the Department has not accepted the provider suggestion relating to delay in the application of the inflation factor. It notes in this regard that the inflation factor is intended only to ensure that the value of uncompensated services remains constant, and does not operate as a "penalty."

12. Audits of Prior Unassessed Years of Compliance

A problem exists with respect to how to treat facilities whose compliance with the 1979 rules has not been assessed by the Secretary for some or all of the period between 1979 and the effective date of these rules. The proposed rules addressed this issue by proposing two options. Each facility could be credited with an amount of creditable services calculated by the Department based on the facility's reported data concerning compliance, adjusted by a factor derived from a review of all assessments conducted to date. Alternatively, they could hire an independent auditor to certify the amount of uncompensated services provided to supply a basis for adjusting the Department's calculation. *See,* proposed § 124.511(b)(1)(ii).

This proposal elicited widespread criticism. Many facilities and consumer groups alike contended that the proposed approach lacked any statistical validity. Facilities argued that it would penalize facilities with better-than-average compliance, as the sample would contain assessments of a large number of noncomplying facilities. Consumer groups, on the other hand, argued that the approach would unduly benefit noncomplying facilities. A number of consumer groups argued that the proposal was also unfair in that it permitted credit to be increased without any parallel provision for decreasing credit.

The Department is persuaded by the comments received and has abandoned the approach proposed. Instead, it will conduct assessments of prior unassessed years for each facility to determine a facility-specific credit. *See,* § 124.511(b)(2) below. This approach accommodates the concerns of both providers and consumers with crediting facilities with amounts based on assessments of other facilities. It likewise responds to the consumer concern with the one-sided nature of the proposed rule, as, under the rule below, there is no longer any provision for facilities to obtain an adjustment through an independent audit.

13. Small Obligation Compliance Alternative

Based on a recent study of Hill-Burton associated administrative costs conducted by A.D. Little, Inc., "Evaluation of the Hill-Burton Program Administrative Compliance Costs", the proposed rules proposed a compliance alternative very similar to that available to public facilities, for facilities with small annual obligations. Under the proposed rules, facilities with annual obligations of $10,000 or under (in the year the rules become effective) could be exempted from the procedural and administrative requirements of the

regulations if the Secretary certified that they conducted a program of providing health services at no or a substantially reduced charge to persons who are unable to pay therefor. A facility would apply for certification by submitting a description of its program of discounted health services. Once granted, the certification would remain in effect until withdrawn by the Secretary. The Secretary could withdraw certification where the Secretary determined that there had been a material change in the factors upon which the certification was based or a material failure by the facility to comply with its continuing obligations under the certification.

A number of consumer organizations objected to the proposed compliance alternative. Several opposed the proposed alternative on the ground that it constituted an exemption from the statutory requirement, for which there is no statutory basis. Others opposed the alternative on the ground that the asserted basis for the requirement was not sound. In this regard, commenters argued that the findings of the cited report applied to the whole universe of Hill-Burton assisted facilities, and the administrative costs of facilities with small obligations were in fact substantially lower. Others argued that the administrative costs findings of the report were misleading, as approximately 90% of all Hill-Burton costs are consumed in routine admissions screenings, so that the actual annual incremental costs to facilities were in the $780 range, rather than the $7,800 range. A State agency argued that the alternative violated the equal protection clause, as it was not justified by any administrative cost differential.

Still other commenters objected to the proposed alternative on the ground that it was unfair to small communities, where a $10,000 obligation may be quite significant. One commenter objected to the proposed test for "programs of discounted health services" on the ground that even "objective" eligibility tests may be arbitrary. Another commenter sought clarification of the means for calculating the $10,000 qualification level, questioning whether, in calculating if a facility met the $10,000 annual compliance level test, it could apply previously earned excesses to reduce its annual compliance level for the year. A couple of commenters objected to the proposed policy on the ground that the compliance history of facilities with small obligations is poor. Another objected that the alternative was illegal because it required no record-keeping.

The rules below retain the compliance alternative for facilities with small annual obligations, although several major changes have been made in response to the public comments. The Department agrees that the provisions relating to the qualification level needed refinement. Accordingly, the rule below provides that the qualification level is to be determined, for Title VI-assisted facilities, by computing the facility's average annual compliance level over the remainder of its obligation, factoring in any past deficits. *See,* § 124.514(b)(1)(i). At the same time, since the "buy out" formula, which provides the basis for the calculation, has no application to facilities assisted under Title XVI, a new qualification level has been added to permit such facilities to qualify for the compliance alternative. *See,* § 124.514(b)(1)(ii). The level for Title XVI-assisted facilities is biased heavily against permitting facilities with large outstanding deficits to qualify. *Id.* The qualification level is also, under the rules below, a performance level; *see* § 124.514(d). Moreover, since the performance level under the rules below is pegged to a formula that takes into account outstanding deficits, it means that a complying facility will be making up its deficit as it complies with its certification. To facilitate this, the period of obligation for certified facilities is concomitantly extended. *See,* § 124.514(e)(1) below. This feature of the rules below eliminates the need for deficit make-up provisions analogous to those applicable to public facilities certified under § 124.513. Rather, the rules below provide only that certified facilities must make up any outstanding deficit in accordance with § 124.503(b) following withdrawal of certification. *See,* § 124.514(e)(2) below.

The Department disagrees with the comments objecting to the compliance alternative as unsupported by the A.D. Little study. The charge that 90% of the $7,800 average administrative costs identified in the study were attributable to routine pre-admission screening costs is wrong. The study considered only those costs directly attributable to Hill-Burton regulatory requirements in arriving at the $7,800 figure. The contention that the study fails to support the policy because the average compliance costs of facilities with small obligations is proportionately less than that of facilities with large obligations is likewise in error. The study found that the average administrative compliance costs for hospitals were $9,510, for long-term care facilities (nursing homes, TB hospitals, chronic disease hospitals, and rehabilitation centers), $4,268, and for all other facilities (public health centers, community mental health/retardation centers, State health laboratories and independent outpatient centers) $5,009. However, these compliance costs become more significant when compared to base compliance levels. For Fiscal Year 1984 base compliance levels averaged $155,000 for hospitals, $49,000 for long-term care facilities, and $33,000 for all other facilities. Thus, Hill-Burton administrative costs were on average about 6% of the base compliance level for hospitals, 12% of the base compliance level for long-term care facilities and 21% of the base compliance level for "other" facilities, which, on average, have the smallest obligations. Thus, in the Department's view, the study establishes that the compliance costs associated with the regulations weigh disproportionately heavily on facilities with small annual obligations.

The Department disagrees with and has not accepted the remainder of the comments. With regard to the question of whether it has the legal authority to "exempt" these facilities from their assurance obligation, it would agree that it lacks such authority, but it disputes that § 124.514 constitutes an exemption. Rather, it constitutes an alternative compliance standard. It cannot be disputed that the Secretary has discretion, under 42 U.S.C. 300s(3), to prescribe standards of compliance; it likewise cannot be argued that the compliance standards of the 1979 rules are immutable or are the only ones that can effect the statutory purpose. Rather, the Secretary has discretion, under section 300s(3), to determine, based on experience, what those standards should be and to change them as circumstances change. For the reasons discussed above, the Secretary remains convinced that a compliance alternative is needed for facilities with small annual obligations and that the Secretary has the legal authority to establish such an alternative. The Department rejects as completely unfounded the criticism of the compliance alternative on the grounds that it requires no reporting or record-keeping; *see,* §124.509(b), § 124.510(b), § 124.511(a)(3), § 124.512(c)(3). One commenter noted that "objective" eligibility criteria may be arbitrary. The Department, however, notes that the term "objective" must be construed in terms of the related term "financial criteria," and thus is not arbitrary. The Department's experience with the related provision in § 124.513 has indicated little problem in this area. Finally, although the Department agrees

that in a small, often rural community, a $10,000 Hill-Burton obligation may be significant, it disputes the premise of this criticism, *i.e.*, that certification under this section will deprive the community of uncompensated services. Rather, the compliance alternative is available only to facilities that have a program of "discounted health services." Furthermore, the facilities that are certified under this section continue to be held to a dollar volume of uncompensated (or "discounted") services which they must provide, and they must make up deficits if they fail to meet this level. *See*, § 124.514(d) below. Thus, the compliance alternative is structured so that the communities served by such facilities will not lose uncompensated services.

14. Community and Migrant Health Centers Compliance Alternative

Under proposed § 124.503(d), a center funded under either section 329 or section 330 of the PHS Act would be considered to have met its uncompensated services obligation in each year in which it was in compliance with the conditions of its grant relating to provision of services at a discount.

This proposal elicited very little comment. One community health center asked that the provision be made retroactive. Another provider asked that the provision be extended to so-called freestanding National Health Service Corps (NHSC) clinic sites, on the ground that they are likewise required by Federal regulations to provide discounted services. A consumer group objected that the provision was illegal, on the ground that there is no statutory basis for exempting any class of facilities from the obligation.

The Department agrees that the rationale supporting the policy for community and migrant health centers applies equally to certain NHSC sites, at least where such sites are functionally the same as a community or migrant health center, as is the case where the entire medical services of the site are provided by the Corps professionals. It has thus revised the proposed rule to cover certain NHSC clinic sites, but only to the extent the services provided by the NHSC health professional(s) constitute the entirety of the services provided by the facility. While the Department has not accepted the suggestion that the provision be made retroactive, it recognizes that the commenter has raised a valid concern. It has thus revised the provision to include deficit make-up provisions that parallel those applicable under § 124.513. *See*, § 124.515(b) below.

The Department disagrees with the consumer contention that the proposed § 124.503(d) is illegal. As stated in the preamble to the proposed rules, it believes that facilities which are in compliance with the terms of a grant under section 330 or 329 (or an agreement under section 334) of the PHS Act are, in fact, providing a reasonable volume of services to persons unable to pay, and thus should not be required to comply with the conflicting procedural requirements of Subpart F. However, it recognizes that the placement of this provision in § 124.503 in the proposed rules was confusing in this regard. It has thus placed the provisions relating to community and migrant health centers following the other compliance alternatives in a new § 124.515, to make clear that these provisions in fact simply amount to an alternative means of complying with the statutory assurance.

15. State Agencies

Proposed § 124.513 proposed to broaden the types of State agencies with which the Secretary could contract to carry out the assurances program. This proposal attracted no substantive comment and is retained as proposed in the rules below. *See*, § 124.516.

## III. Regulatory Flexibility Act and Executive Order 12291

The Regulatory Flexibility Act (5 U.S.C. Ch. 6) requires the Federal Government to anticipate and reduce the impact of rules and paperwork requirements on small businesses. The Secretary certifies that this rule will not have significant economic effect on a substantial number of small entities. Therefore, it does not require a Regulatory Flexibility Analysis.

The Secretary has also determined that this final rule is not a "major rule" as defined under E.O. 12291, because it will not have an annual effect on the economy of $100 million or more, or otherwise meet the criteria for which a regulatory impact analysis is required.

## IV. Information Collection Requirements

Sections 124.504 (a) and (c), 124.507, 124.509 (a) and (b), 124.510 (a) and (b), 124.511(a) 124.513(c), 124.513(d)(2)(ii)(B), and 124.513(d)(2)(iii)(B)(2) of this rule contain information collection requirements which have been approved, under control number 0915-0077 by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980.

Sections 124.509(c), 124.514(c), 124.515(b)(2)(ii), and 124.515(b)(3)(ii)(B) of this rule contain new information collection requirements subject to approval by the OMB. We will be submitting an information collection request to the OMB for approval of these requirements under section 3507 of the Paperwork Reduction Act of 1980 (44 U.S.C. 3507). These requirements will not be effective until the Department obtains OMB approval. When approval is obtained, a notice will be published in the **Federal Register** announcing the effective date of these requirements.

## V. List of Subjects in 42 CFR Part 124

Grant programs—health, Health facilities, Loan programs—health, Low income persons, Reporting and record-keeping requirements.

Accordingly, the Department of Health and Human Services hereby amends Part 124 of 42 Code of Federal Regulations by revising Subpart F to read as follows:

Dated: August 4, 1987.

**Robert E. Windom,**

*Assistant Secretary for Health.*

Approved: October 22, 1987.

**Otis R. Bowen,**

*Secretary.*

## PART 124—[AMENDED]

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

Sec.



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

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

**§ 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 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 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, or § 124.515, 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 peer review 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, or § 124.515, 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) or § 124.514(c)(2), as applicable, or pursuant to the terms of the applicable grant or agreement as provided in § 124.515. 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 peer review organization that it disapproved the services under section 1155(a)(1) or section 1154(a)(1) of the Social Security Act.

**§ 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 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.

(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 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, or § 124.515, 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, multiplied 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.

### § 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.

(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);

(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; 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) 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;

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

**§ 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 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 this method is applicable to all persons in Category B; and

(v) 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), 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), the facility must provide uncompensated services without charge to all applicants in Category A and Category B 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.

**§ 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

(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.

**§ 124.508 Cessation of uncompensated services.**

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

**§ 124.509 Reporting requirements.**

(a) *Facilities not certified under § 124.513, § 124.514, or § 124.515*—(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 Administrator [1] 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.* A facility certified under § 124.513 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] The addresses of the HHS Regional Offices are set out in 45 CFR 5.31.

(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.

**§ 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 subparagraph (A) of this paragraph, 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 subparagraph (A) of this paragraph, is at or less than $10,000, adjusted as provided in paragraph (b) (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 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 precedures 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.

**§ 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

124.505, (b)(2)

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

**§ 124.516 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.

[FR Doc. 87-27316 Filed 12-2-87; 8:45 am]

[**Editorial Note:** This reprint incorporates corrections published in the **Federal Register** of Monday, December 21, 1987.]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 124

RIN 0905–AE06

## Medical Facility Construction and Modernization; Requirements for Uncompensated Services for Persons Unable to Pay

AGENCY: Public Health Service, DHHS.

ACTION: Final rule.

SUMMARY: The rules below revise the rules currently governing how certain health care facilities, assisted under Titles VI and XVI of the Public Health Service Act, fulfill the assurance given in their applications for assistance that they would provide a reasonable volume of services to persons unable to pay for such services. The revisions below amend the rules to permit facilities that provide substantial free or below cost medical services but nonetheless cannot receive credit for such services under current requirements with an alternative method of compliance that will enable them to fulfill their uncompensated services obligations.

DATES: This rule is effective on August 30, 1994.

FOR FURTHER INFORMATION CONTACT: Mr. Eulas Dortch, 301–443–5656.

SUPPLEMENTARY INFORMATION: On November 4, 1993, the Secretary of Health and Human Services published a Notice of Proposed Rulemaking (NPRM) proposing to revise the rules governing what is popularly known as the Hill-Burton uncompensated services program. 58 FR 58828. Health care facilities covered by the program received construction assistance under two titles of the Public Health Service Act, Title VI (the "Hill-Burton Act", 42 U.S.C. 291, *et seq.*) and Title XVI (42 U.S.C. 300q, *et seq.*). Under both titles, facilities receiving construction assistance have been required, as a condition of receiving the construction assistance, to provide an assurance that "there will be available in the facility or portion thereof to be constructed or modernized a reasonable volume of services to persons unable to pay therefor * * *." 42 U.S.C. 291c(e)(2). See also 42 U.S.C. 300s-1(b)(1)(K)(ii). This assurance is known as the "uncompensated services assurance."

### Background of the Regulations

The groundwork of the present uncompensated services compliance requirements was laid by

comprehensive regulations that were issued in 1979. 44 FR 29372 (May 18, 1979). The 1979 regulations established numerous compliance requirements for uncompensated services programs. These included requirements for a minimum level of uncompensated services to be provided by facilities, an annual compliance level (ACL) of uncompensated services to be provided, make-up of any deficit in meeting the ACL, national eligibility criteria for determining who is unable to pay, notice requirements, requirements regarding the timing and documentation of eligibility determinations, reporting and recordkeeping requirements, and so on.

When experience with the 1979 regulations showed that they created substantial compliance problems for a number of public facilities, which were amassing large deficits despite serving large numbers of indigent patients on a free or below cost basis, the regulations were amended. A compliance alternative for public facilities, which is codified at 42 CFR 124.513, was created. 51 FR 33208 (Sept. 18, 1986). The public facility compliance alternative provides that a publicly owned and operated facility or quasi-public facility may be certified if it provides health services to eligible persons under a program of discounted health services and either received for the past three fiscal years at least 10 percent of its total operating revenue from state and/or local sources to cover operating deficits attributable to the provision of discounted health services, or provided in those fiscal years uncompensated services or free or discounted health services in an amount equal to or greater than twice the facility's annual compliance level. The facility must comply with separate reporting and recordkeeping requirements and is required only to comply with the requirements relating to certified facilities. A facility may make up previously assessed deficits by showing that it met the conditions for certification in the deficit period; a Title VI facility may also make up a previously assessed deficit by remaining certified after its original period of obligation for a period equal to the deficit period, while a Title XVI facility that cannot show that it met the conditions of certification in the deficit period must make up any remaining deficit whenever its certification is withdrawn. A facility with an unassessed deficit may submit an independent certified audit to establish that no, or a lesser, deficit exists.

In 1987, the Secretary again revised the 1979 regulations. 52 FR 46022 (Dec. 3, 1987). As pertinent here, an additional compliance alternative for facilities with annual obligations of $10,000 or less was created. See § 124.514. This alternative was adopted to bring the administrative costs of compliance for such facilities more into line with the actual level of uncompensated services available, with the requirements applicable under § 124.514 resembling those applicable under the public facility compliance alternative.

**Proposed Rules**

In the NPRM, the Secretary proposed an additional compliance alternative designed to address the compliance problems of another class of facilities whose operational characteristics have created intractable compliance problems, but which cannot qualify for the existing compliance alternatives. Many of these facilities provide substantial amounts of free or below cost services, generally because they were created to provide services at no or a nominal charge to all persons, or they serve an indigent population that is entirely covered by third-party programs such as Medicaid. These facilities, which are generally private, nonprofit organizations, include facilities such as sheltered workshops, crippled children rehabilitation facilities, cerebral palsy centers, chronic disease hospitals, Goodwill Centers, facilities for the blind, mental health centers, and Easter Seal Centers. Based on experience monitoring such facilities' compliance with the uncompensated services regulations since 1979, the Department determined that many such facilities have accumulated large uncompensated services deficits, typically because their policies of not charging or of serving populations covered under governmental indigent care programs preclude receiving credit under the uncompensated services regulations for the free and below cost care they in fact provide.

The Department identified 180 private, nonprofit outpatient, rehabilitation, and community mental health center facilities with outstanding uncompensated services obligations which were likely to have provided a large volume of free or below cost care while receiving little or no uncompensated services credit. A survey of 28 of these confirmed that there are a number of facilities for which compliance with the uncompensated services requirements is difficult or impossible, given their charging policies, legal requirements applicable to their operations, characteristics of their patient populations, or some combination of these factors, but which clearly provide health services without regard to ability to pay.

Accordingly, the Secretary proposed to adopt a compliance alternative for private, nonprofit facilities which provide a substantial amount of services without regard to ability to pay, but which find it difficult, if not impossible, to comply with the present uncompensated services requirements. The proposed compliance alternative was substantially similar to the public facility compliance alternative with respect to requirements for reporting, recordkeeping, and the make-up of deficits. However, the eligibility criteria differed somewhat. Under the proposed rule, a facility could qualify for the compliance alternative if it was a private, nonprofit entity falling into one of two categories: either (1) it received no monies directly from patients with incomes up to twice the poverty level (exclusive of certain deductible and coinsurance amounts and other required collections), or (2) it received for the three most recent fiscal years at least 10 percent of its non-Medicaid and non-Medicare operating revenue from philanthropic sources to cover operating deficits and either provided services under a "program of discounted health services" or provided all services to all persons at no or a nominal charge (exclusive of certain deductible and coinsurance amounts and other required collections). With respect to the first category, the NPRM stated that in the Department's view those facilities that collect no monies from patients with incomes up to twice the poverty level are meeting the statute's objectives. Similarly, with respect to the second category, the proposed percentage of private philanthropic support was considered to be a proxy for tax support in the public facility context, as such monies are generally contributed to fund services which are deemed essential or worthwhile, but which are not self-supporting. The "program of discounted health services" criterion is analogous to a similar criterion in the public facility compliance alternative, and reflects a recognition that many such facilities have in place a mechanism for determining eligibility for such services by screening for ability to pay. The rationale for the other criterion is self-evident: Clearly, facilities that provide all services at no or a nominal charge are adequately serving those in their patient population who are unable to pay. The NPRM also solicited comment on whether the compliance alternative should be

expanded to cover public facilities that do not qualify for the public facility compliance alternative but whose operational characteristics are similar to the private, nonprofit entities the alternative would cover.

**Public Comment and the Department's Responses**

The Department received 23 comments on the proposed rules, principally from rehabilitation and other facilities and provider associations. While most of the comments received were in favor of the proposed compliance alternative in principle, many suggested specific changes to the proposed policies. The comments and the Department's responses thereto are summarized below.

*1. Criteria for Certification.*

a. Inclusion of Public Facilities

A number of commenters recommended that the criteria for certification be changed to permit the inclusion of public facilities that otherwise meet the criteria for certification. They argued that there is operationally no difference between such facilities and non-profit facilities that meet the criteria, and that it is unreasonable to penalize public facilities just because they are public. The Department agrees with these comments and has changed the rules accordingly, by eliminating proposed § 124.516(b)(1), which would have restricted the compliance alternative to private, nonprofit facilities.

b. No Monies Received From the Indigent

Proposed § 124.516(b)(2) would have established, as one alternative criterion for certification, that a facility received no monies directly from persons with incomes up to twice the poverty level, exclusive of amounts charged or received for purposes of obtaining reimbursement under third party programs. Several commenters urged that this criterion be revised to permit receipt of funds from such persons, on the grounds that it is unrealistic to expect a facility to receive *no* money from such persons. It was suggested that the criterion be revised to permit receipt of funds up to some amount, such as 10 percent of operating revenues. The Department has not accepted this suggestion. This criterion was intended to accommodate those exceptional facilities which routinely provide all services at no charge to persons unable to pay or which entirely serve populations ineligible for uncompensated services and are thus unable to comply with the regulations. Facilities that collect monies from patients with incomes below twice the poverty level do not come within the intent of this criterion. It should be noted, however, that such facilities may nonetheless be able to qualify for the compliance alternative under a different criterion of the regulation, if they have a "program of discounted health services" and receive the requisite amount of philanthropy. See § 124.516(b)(2) below.

Another suggestion made with respect to this criterion was that amounts collected from patients as part of their Medicaid "spenddown" be considered to be included under the exclusionary language of this section, so that collection of such monies by a facility would not render it ineligible under this criterion. This suggestion has likewise not been accepted. Spenddown amounts are clearly not within the scope of the exclusionary language as written, as Medicaid eligibility does not exist until the patient has spent down the requisite amount, and therefore they are not amounts charged that are reimbursable. Nor do we think the language should be revised to permit inclusion of spenddown amounts in the amounts permitted to be charged or claimed. As stated above, this criterion is intended to cover a narrow class of facilities—ones which can be considered to be meeting their Hill-Burton obligation because they are in fact not receiving monies directly from any patients who would otherwise be eligible for Hill-Burton uncompensated services. Permitting collection of spenddown amounts would thus not be consistent with the intended scope of this criterion.

This criterion has been revised, however, to require that the facility demonstrate that it met the criterion for the preceding three fiscal years. This revision brings this criterion into line with the 10 percent philanthropy criterion of § 124.516(b)(2), which also requires a demonstration of compliance over the preceding three years. The purpose of the three-year demonstration in both cases is to give the Secretary a basis for the conclusion that a facility applying for certification in fact comes within the intended scope of the compliance alternative because of its characteristics and problems, and that certification is not made based on what may be a one-time aberration in the facility's circumstances. See § 124.516(b)(1) below.

Another commenter suggested that, in view of the difficulty many nursing homes have in finding individuals who are eligible for uncompensated services and not also eligible for Medicaid, the Department create a new eligibility category for persons in nursing homes with incomes up to four times the poverty level. In fact, the Secretary is considering such a change to the regulations; an NPRM proposing to establish a new "Category C," consisting of persons with incomes up to three times the poverty level was recently published. 59 FR 15693 (April 4, 1994). It should be noted that, should this latter policy subsequently be adopted, the Secretary would expect to revise § 124.516(b)(1) below to be consistent with the revision in the underlying regulations.

c. Definition of "Philanthropy"

Consistent with the elimination of the restriction of the compliance alternative to private facilities, the Department has also broadened the examples of "philanthropy" in the new § 124.516(b)(2)(i). As revised, the term "philanthropy" includes state and/or local funding, as it is anticipated that most philanthropic funding for public facilities will originate from such sources.

The term "philanthropy" has also been clarified by the addition of the phrase "to cover operating deficits attributable to the provision of discounted services." The added words, among other things, make clear that philanthropic state or local funding within the scope of this section is different than state or local funds received under entitlement programs, which have long been considered not to be "uncompensated services"; see § 124.505(a). The additional language imposes a similar restriction on other forms of philanthropy.

Several commenters suggested that the term "philanthropy" be further revised to include interest earned on donated funds. However, since it is the Department's view that interest on donated funds is clearly from a "philanthropic source," further clarification of the regulation in this respect is not needed.

d. Program of Discounted Services

One provider group opposed the eligibility criterion permitting certification where a facility has a "program of discounted services." The group argued that this provision would create a problem under Medicaid and Medicare, the rules of which prohibit those programs from subsidizing other patients. The Department does not believe that this is a problem, since the discounts made to patients under a facility's discounted health services

program are not required to be reflected in charges to those programs. Certainly, this has not proved to be a problem with facilities operating under the general compliance requirements or with facilities certified under the public facility compliance alternative, which contains the same eligibility criterion.

The definition of "program of discounted health services" has been revised, however, by the addition of language making clear that charges may be made under such a program for the purpose of obtaining third party reimbursements. This policy was discussed in the preamble to the proposed rule, but was omitted from the proposed rule itself. The change simply makes the policy of this section consistent with the policy throughout the remainder of the subpart that third party collections are to be encouraged. See § 124.505(a).

e. No or Nominal Charge Policies

This section has likewise been revised by the addition of the language discussed in the preceding paragraph. One comment questioned the criterion set out in the proposed rules pertaining to making "all services of the facility available to all persons at no or a nominal charge." It expressed the concern that a hospital could qualify for the compliance alternative under this criterion simply by designating some narrow group of services, then making them available for free or at a nominal charge, while continuing to charge everyone fully for the facility's other services. We do not share the commenter's concern, as the rule below expressly states that, in order to come within this criterion, the facility must "make[ ] all services of the facility available to all persons * * *" See § 124.516(b)(2)(ii)(B) below.

f. Other Eligibility Criteria

Other proposals for eligibility criteria were received. Several commenters suggested that a facility's Medicaid census be a basis for eligibility; these commenters suggested that facilities with a 70 percent or greater Medicaid census be eligible for the compliance alternative. One commenter suggested that long-term care facilities with characteristics "similar" to the proposed eligibility criteria likewise be considered to be eligible for the compliance alternative.

The Department is not persuaded that it should create a special eligibility criterion based on a facility's Medicaid/Medicare census. Clearly, those facilities that serve large numbers of Medicaid or Medicare recipients are not precluded from qualifying under one of the criteria below, if they in fact meet those criteria. Indeed, we do not think it would be consistent with the theory underlying the compliance alternative to craft such an eligibility criterion. The theory of the compliance alternative is that the facilities who come within it need the alternative because compliance with the general compliance standards is difficult, if not impossible, for them because of their operational characteristics, even though they are clearly providing free or below cost services to "persons unable to pay." However, compliance with the general compliance standards is not impossible for a facility with a 70 percent Medicaid/Medicare census which charges the remaining 30 percent of its patient population. After all, if none of the remaining 30 percent of the facility's patient population meets the eligibility criteria of § 124.505, the facility will qualify for the compliance alternative under § 124.516(b)(1) below. Thus, it must be assumed that the intent of the proposed revision would be to permit facilities to qualify for the compliance alternative even though they charge patients who meet the Hill-Burton eligibility criteria and who thus could be provided uncompensated services.

With respect to the comment regarding long-term care facilities, the Department has not created a special criterion for such facilities. If such facilities meet the eligibility criteria below, they may be certified under the new compliance alternative. We note, moreover, that the proposed change in eligibility criteria for nursing homes may well relieve some of the particular difficulties of nursing homes in complying with the general compliance standards.

*2. Documentation*

A number of comments expressed support for minimizing the reporting and recordkeeping required of qualifying facilities under the proposed compliance alternative. One hospital, however, opposed the proposed rules on the grounds that they simply created an additional layer of reporting and recordkeeping requirements, stating that the existing requirements work well. It should be emphasized that the compliance alternative is not meant to create an additional set of requirements for facilities already complying with the general compliance requirements at §§ 124.501–124.512; rather, the compliance alternative below is designed to relieve facilities which qualify for it from the burden of complying with the general compliance requirements. Consistent with this approach, the reporting and recordkeeping required for qualifying facilities is different from that required of most facilities and should generally be considerably less than that under the general compliance standards. In any event, a facility that is not certified under the compliance alternative does not have to comply with the reporting and recordkeeping requirements applicable to those facilities which are certified; concommitantly, a facility that is certified under the compliance alternative is not required to comply with reporting and recordkeeping requirements other than those that apply to certified facilities. A facility always has the option of continuing to comply with the general compliance requirements; it can thus ignore the compliance alternative completely if it decides that compliance with the general compliance requirements makes more sense for it. Thus, we do not think that this particular concern is justified.

A couple of commenters pointed out that the proposed means of demonstrating that a facility meets the eligibility criteria—through audited financial statements—would not necessarily suffice, depending on the criterion involved. They pointed out that, for example, audited financial statements do not necessarily set forth philanthropic sources in the level of detail required, or establish a facility's charging policies. They suggested that the rule be amended to require facilities to contract for such information as part of their audits. The Department agrees with the observation made about the limitations of audited financial statements, but does not agree with the remedy proposed. Rather, it is our view that documentation sufficient to establish sources of philanthropy, charging practices and so on can be provided by other means, and we are reluctant to put facilities to the added expense of contracting for audit services that they would not otherwise need. Thus, § 124.516(c)(1) below has been revised to add a requirement for "other documents" to cover the concern raised by the commenters. The Department will issue program instructions clarifying what other documents may be required in specific instances.

*3. Deficits*

One commenter suggested that the proposed rules be revised to permit facilities to treat deficits resulting from Medicaid underpayments as justifiable deficits. However, we are not accepting this comment, as it is not pertinent to the compliance alternative. The rules below do not distinguish between types of deficits for purposes of deficit make-up under the alternative, unlike the

general compliance requirements, which do draw such a distinction. Compare § 124.516(d)(2) below with § 124.503(b). Thus, under the compliance alternative, a certified facility with a noncompliance deficit may make up the deficit in precisely the same manner as a certified facility with a justifiable deficit.

*4. Other Comments*

Several comments questioned whether vocational services could be counted as uncompensated services under the compliance alternative; the facilities concerned stated that they have difficulty meeting the ACL since they do not receive credit for vocational services they provide. The compliance alternative below should relieve this problem for facilities that are certified, however. Certified facilities will not have to provide a set amount of uncompensated services, unlike facilities operating under the general compliance requirements. Thus, so long as certified facilities provide some medical services and otherwise remain in compliance with the requirements for certification, they will be considered to be in compliance with their uncompensated services assurance.

In view of the fact that the rules below relieve restrictions on facilities that apply and are certified for the compliance alternative and impose no additional duties or obligations on other facilities, delay in the effective date of these rules is not required under 5 U.S.C. 553. For the same reasons, the Secretary hereby finds that good cause exists for not delaying the effective date of the rules below. The rules are accordingly effective upon publication.

**Regulatory Flexibility Act and Executive Order 12866**

The rule below would generally maintain the existing procedural and reporting requirements for the majority of obligated facilities, but significantly lessen them for certain private, nonprofit or public facilities. The Department has determined that the impact would not approach the annual $100 million threshold for major economic consequences as defined in Executive Order 12866. Therefore, a regulatory impact analysis is not required.

Consistent with the provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Secretary certifies that this rule will not have a significant economic impact on a substantial number of small entities.

**Paperwork Reduction Act of 1980**

This final rule contains information collections which have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1980, and assigned control #0915–0171.

The underlying purpose of this rule is to decrease recordkeeping, reporting, and notification burden for the charitable facilities. Facilities certified under the charitable facility compliance alternative will no longer be required to maintain extensive records on uncompensated services (124.510(a)), but instead will have to maintain only records which document its eligibility for the compliance alternative (124.510(b)). We believe this recordkeeping requirement imposes no additional burden because these documents are ordinarily retained by facilities. This change is expected to reduce the recordkeeping burden by 75 hours per facility per year.

Similarly, reporting burden will be reduced. Charitable facilities will be required to apply once for the certification (124.516(c)), and thereafter will need only to certify their continued eligibility annually (124.509(b)). Currently, facilities in deficit status, which include most of the charitable facilities, must file a report each year which documents the amount of uncompensated care provided (124.509(a)). This change in reporting requirements is expected to reduce the reporting burden by 6 hours per facility in the first year, and by 13.5 hours per facility in subsequent years.

Finally, notification/disclosure burden will be eliminated, because the facilities will no longer be required to: (1) Publish a notice each year of the availability of uncompensated services (124.504(a)); (2) provide individual written notices to each person seeking service in the facility (124.504(c)); or (3) provide a determination of eligibility to each person applying for uncompensated services (124.507). These changes are expected to reduce the notification burden by 380 hours per facility per year.

All sections of the regulations that contain reporting, recordkeeping, or notification/disclosure requirements have been approved by OMB under the Paperwork Reduction Act (OMB) #0915–0077 and #0915–0171. The title, description, and respondent description of the information collections are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

The addition of the requirement for "other documents" in § 124.516(c)(1) will not affect the burden because the other documents are expected to be readily available materials.

The estimate of 150 applicants was based on a review, prior to development of the NPRM, of data on the kinds of facilities expected to qualify for the alternative. A recent re-review of the list of facilities indicated that 30 of the facilities have completed their obligations. With the addition of public facilities in the qualifying criteria, we expect approximately 30 additional facilities to apply for certification.

*Title:* Charitable Facility Compliance Alternative (42 CFR part 124 subpart F).

*Description:* Information will be collected from facilities requesting certification under the compliance alternative for the purpose of determining whether the required criteria for qualification have been met.

*Description of Respondents:* Public and private non-profit institutions.

ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDEN

| Section | Activity | Annual number of respondents | Annual frequency | Average burden per response | Annual burden hours |
|---|---|---|---|---|---|
| 124.516(c) | Procedures for certification[1] | 150 | 1 | 6.0 | 900 |

[1] Approximately 150 facilities are expected to be certified under the proposed charitable facility compliance alternative in the first year. We expect no new applications in subsequent years; therefore, there will be no burden beginning in year 2.

We received no public comments on the estimated public reporting burden and it remains the same as that contained in the proposed rule.

**List of Subjects in 42 CFR Part 124**

Grant programs—Health, Health facilities, Loan programs—Health, Low income persons, Reporting and recordkeeping requirements.

Dated: July 1, 1994.

**Philp R. Lee,**

*Assistant Secretary for Health.*

Approved: August 11, 1994.

**Donna E. Shalala,**

*Secretary.*

For reasons set out in the preamble, part 124, subpart F, of title 42 of the Code of Federal Regulations is amended to read as follows:

## PART 124—[AMENDED]

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

1. The authority citation for 42 CFR part 124, subpart F, continues to read as follows:

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

2. Section 124.502 is amended by revising the first sentence of paragraph (m)(1) and revising paragraph (m)(2) to read as follows:

**§ 124.502 Definitions.**

* * * * *

(m) * * *

(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.

* * *

(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 peer review organization that it disapproved the services under section 1155(a)(1) or section 1154(a)(1) of the Social Security Act.

3. Section 124.508 is amended by revising the heading and introductory text of paragraph (a) to read as follows:

**§ 124.508 Cessation of uncompensated services.**

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

* * * * *

4. Section 124.509 is amended by revising the heading of paragraph (a) and by revising the heading and introductory text of paragraph (b) to read as follows:

**§ 124.509 Reporting requirements.**

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, or § 124.516.* * * *

* * * * *

(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:

* * * * *

5. Section 124.510 is amended by revising the heading of paragraph (a) and by revising the heading and the first sentence of paragraph (b) to read as follows:

**§ 124.510 Record maintenance requirements.**

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, or § 124.516.* * * *

* * * * *

(b) *Facilities certified under § 124.513, § 124.514, or § 124.516.* A facility certified under § 124.513, § 124.514, or § 124.516 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 applicable requirements of this subpart in any fiscal year, including those documents submitted to the Secretary under § 124.513(c), § 124.514(c), or § 124.516(c). * * *

* * * * *

6. Section 124.511 is amended by revising the first sentence of paragraph (a)(3) and by revising paragraph (b)(1)(iii)(C) to read as follows:

**§ 124.511 Investigation and determination of compliance.**

(a) * * *

(3) When the Secretary investigates a facility, the facility, including a facility certified under § 124.513, § 124.514, § 124.515, or § 124.516, shall provide to the Secretary on request any documents, records and other information concerning its operation that relate to the requirements of this subpart. * * *

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(C) The facility had procedures in place that complied with the requirements of §§ 124.504(c), 124.505, 124.507, 124.509, 124.510, 124.513(b)(2), 124.514(b)(2), 124.515, and 124.516 (b)(1) or (b)(2), as applicable, and systematically correctly followed such procedures.

* * * * *

7. Section 124.512 is amended by revising the introductory text of paragraph (b) and by revising paragraph (c)(1) to read as follows:

**§ 124.512 Enforcement.**

* * * * *

(b) A facility, including a facility certified under § 124.513, § 124.514, or § 124.516, 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:

* * * * *

(c) * * *

(1) Have a system for providing notice to eligible persons as required by § 124.504(c), § 124.513(b)(2), § 124.514(b)(2), or § 124.516(b)(2)(ii)(A), as applicable;

* * * * *

8. In subpart F, § 124.516 is redesignated as § 124.517.

9. A new § 124.516 is added to subpart F, to read as follows:

**§ 124.516 Charitable 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 "charitable 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 facility may qualify for certification under this

section if it meets the criteria of either paragraph (b)(1) or paragraph (b)(2) of this section:

(1) It received, for the three most recent fiscal years, 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 purposes of claiming reimbursement under third party insurance or governmental programs, such as Medicaid or Medicare deductible or coinsurance amounts; or

(2)(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 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—

(ii) (A) 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 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; or

(B) 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.

(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 for the three most recent fiscal years or other documents prescribed by the Secretary, sufficient to show that the facility meets the criteria of paragraph (b)(1) or (b)(2) of this section.

(2)(i) Where the facility claims qualification under paragraph (b)(2)(ii)(A) 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.

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

(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 in the Secretary's judgment adequately remedied or otherwise continues.

(2) *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—

(A) Demonstrating to the Secretary's satisfaction that it met the applicable 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 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) 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 paragraph (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 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.

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# Federal Register

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Part II

# Department of Health and Human Services

42 CFR Part 124

Compliance Alternatives for Provision of Uncompensated Services; Final Rule

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**42 CFR Part 124**

**RIN 0906–AA52**

## Compliance Alternatives for Provision of Uncompensated Services

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The rules below revise a compliance alternative applicable to health care facilities with Hill-Burton uncompensated services obligations. The revised compliance alternative provides a more flexible compliance standard for facilities that principally serve nonpaying patient populations by reducing the amount of time needed to qualify for certification under the alternative and by providing for a provisional certification, where a facility is unable to qualify for full certification. The rules below also provide a compliance alternative for obligated facilities with histories of uncompensated services deficits, to enable them to make up the deficits on a timely basis. These revisions have the effect of making it easier for facilities with uncompensated services obligations to meet those obligations, while still ensuring the availability of uncompensated services to persons unable to pay.

**DATES:** This rule is effective on September 26, 2001.

**FOR FURTHER INFORMATION CONTACT:** Mr. Eulas Dortch, 301–443–5656.

**SUPPLEMENTARY INFORMATION:** On October 19, 2000, the Secretary of Health and Human Services published a Notice of Proposed Rulemaking (NPRM) proposing to revise certain requirements relating to the compliance by health care facilities that received assistance under Title VI or Title XVI of the Public Health Service Act, 42 U.S.C. 291, *et seq.*, and 42 U.S.C. 300q, *et seq.* with their assurance, given as a condition of such assistance, that they would provide a reasonable volume of services to persons unable to pay therefor. 65 FR 62976. The regulations establishing the requirements for complying with this assurance, which is commonly known as the "uncompensated services" assurance, are codified at 42 CFR part 124, subpart F. The NPRM proposed to revise one of several current compliance alternatives, to decrease the number of years needed to qualify for the alternative and to permit qualification on a provisional basis. The NPRM also proposed to add another compliance alternative, designed for compliant Title VI-assisted facilities that are in chronic deficit in meeting their uncompensated services obligations.

### I. Background

The Hill-Burton uncompensated services regulations date, in their present form, back to 1979, when regulations containing the basic components of the present regulations were promulgated. 44 FR 29372 (May 18, 1979). The 1979 regulations for the first time established a purely quantitative measure of the statutory "reasonable volume of services"; this quantitative measure was a total obligation measured in dollars, broken down into annual compliance levels. They also provided that a facility that failed to provide in a given year uncompensated services in an amount sufficient to meet its annual compliance level would have a "deficit," which it would have to make up in subsequent years. If not made up, the deficit (along with any additional deficits in later years) would accumulate, and be adjusted by any increases in the medical Consumer Price Index (CPI). *See,* § 124.503(b)(3).

In the years since 1979, the regulations have been amended several times—in 1986, 1987, 1994, and 1995. Aside from the amendment of the basic regulatory structure effected by the 1987 amendment, the rest of the amendments were directed at creating various alternative methods by which facilities could comply with their obligation to provide a reasonable volume of uncompensated services to persons unable to pay. These various "compliance alternatives" appear at §§ 124.513—124.516 of subpart F. Although each of the compliance alternatives is addressed to different types of facilities, all of the facilities that qualify for the compliance alternatives share the same basic characteristics: They provide significant amounts of free or below cost care to persons unable to pay for that care, but, for various reasons, are unable to receive sufficient credit for the care they provide to meet their Hill-Burton uncompensated services obligations under the compliance standards codified at 42 CFR 124.501—124.512. As a consequence, prior to the adoption of the compliance alternatives set out at §§ 124.513—124.516, these types of facilities were generally running uncompensated services deficits, despite providing substantial services on a free or below-cost basis to poor individuals. The compliance alternatives were adopted to address this anomaly.

Over the years since 1979, the number of facilities with an outstanding Hill-Burton uncompensated services obligation has shrunk from approximately 5,000 in 1979 to approximately 650 as of December 31, 2000. Thus, approximately 4,350 Hill-Burton assisted facilities have fulfilled their obligation, provided as a condition of the federal assistance received, to provide a "reasonable volume of uncompensated services to persons unable to pay therefor." However, a number of the remaining Hill-Burton obligated facilities operate compliant, fully 3 expanded uncompensated services programs but fail to receive sufficient uncompensated services requests to satisfy their annual dollar obligation. ("Fully expanded" means that the facilities make available on request, all of their services at no charge to persons unable to pay up to the limit of double the poverty guidelines, Category B eligibility (for facilities other than nursing homes), or triple the poverty guidelines, Category C eligibility (for nursing homes).) Thus, they run Hill-Burton deficits on a chronic basis, and those deficits are adjusted upwards by the percentage change in the medical CPI, pursuant to § 124.503(b)(3). The Department believes that many of these facilities may never be able to make up their deficits under the present requirements.

A few statistics indicate the dimensions of the problem. As of the end of 1998, of the 424 Hill-Burton facilities in deficit, 226 had operated a fully expanded, compliant program for at least a year. Of these 226 facilities, 117 (52 percent, or 28 percent of the total number of facilities in deficit) had operated a fully expanded program for the last three years, and, despite providing over $73 million in uncompensated services in that period, saw their collective deficit increase from $178,724,130 to $180,748,408—an increase of one percent—in the same period. Of these 226 facilities, 64 facilities (28 percent, or 15 percent of the total in deficit) operated fully expanded programs for the last two years, and, despite providing over $36 million in uncompensated services in that period, saw their collective deficit decrease only $10.8 million, or 13 percent for that period, while in 33 of the 64 facilities, the deficits increased. Of the 226 facilities, 45 facilities (20 percent, or 11 percent of the total in deficit) operated fully expanded programs in the last year and, despite providing over $9.8 million in uncompensated services in that period, saw their collective deficit increase from

$57,374,195 to $61,739,838—an increase 4 of 7.6 percent—in that period. It is projected that, because of the increasing deficits a number of these facilities are experiencing, 81 facilities will have at least another 20 years under obligation, and 53 of these 81 will have obligations extending for at least 100 years.

## II. Proposed Rules

The proposed rules shared the objective of the prior compliance alternatives. Like those compliance alternatives, the proposed rules had the goal of enabling facilities, which, by the nature of their operations have great difficulty or find it impossible to meet the dollar volume requirements of the general regulations but nonetheless provide significant uncompensated services to persons unable to pay, to comply with and complete their uncompensated services obligations. A corollary goal of this objective is the reduction or elimination of the uncompensated services deficits of such facilities.

In the case of the amendment to § 124.516, the so-called "charitable facility" compliance alternative, the proposed rule permitted a provisional certification, to make it easier for facilities to qualify for the alternative. Facilities could be provisionally certified, with credit toward their obligation earned during the period of provisional certification if they met the conditions of the provisional certification and with no credit earned if they failed to meet the conditions of the provisional certification. The proposed amendment to § 124.516 thus enabled facilities whose operations in fact qualify them for the charitable facility alternative to start earning credit under that alternative at the earliest possible date, instead of requiring a three-year track record, which was required under the alternative.

In the case of the new compliance alternative set out at § 124.517, the proposed rule provided a means by which facilities in deficit, which remain in deficit despite running procedurally compliant and fully expanded uncompensated services programs, could eliminate their deficits and complete their obligations in a reasonable time frame. The compliance alternative proposed at § 124.517 was to be available to facilities that did not restrict the availability of uncompensated services to their patient population in any way—*i.e.*, they did not restrict the type of services of the facility available on an uncompensated basis, and they did not restrict eligibility for those uncompensated services (for example, by limiting uncompensated services to Category A individuals only, or by charging Category B or, for nursing homes, Category C individuals). In addition, those facilities must comply with the procedural requirements of the standard regulations with respect to notice, eligibility determinations, recordkeeping requirements, and so on. Also, these facilities must provide broad notice of their program to provide services to the poor by:

1. Posting Federally supplied Hill-Burton signs, in prescribed locations, that describe the facilities' obligation to provide uncompensated services to the poor and specify where to file complaints;

2. Publishing notice of their Federal obligation in local newspapers, describing their allocation plan which includes all of their services to eligible persons requesting uncompensated services with incomes up to triple the poverty guidelines for nursing homes and up to twice the poverty guidelines for all other facilities;

3. Distributing, to each person coming to the facilities for services, specific written notification of the Hill-Burton obligation, including the allocation plan, income eligibility criteria, timeframes for facilities to make determinations of patients' Hill-Burton eligibility, and where to make application for Hill-Burton assistance.

Thus, it was clear that Hill-Burton facilities qualifying for the proposed alternative were unique from other facilities located in their areas. Although the non-Hill-Burton facilities may provide charity care, their programs tend not to be publically visible and often are mere writeoffs to charity after they have exhausted efforts to collect payments from the patients.

Where a facility fails to meet its annual compliance level despite the existence of an unrestricted program, the Secretary believes that there is clear evidence that there is insufficient demand for the uncompensated services offered and that the facility should not have to incur a deficit due to a failure of demand. The proposed compliance alternative addressed this issue. In addition, we believe that the compliance alternative will provide a mechanism that will facilitate the goal of making up large deficits. The sheer size of a number of deficits leads to a level of discouragement that can affect a facility's performance. Where this has happened, the existence of the deficit has the perverse effect of harming, rather than helping, the pool of eligible individuals such facilities serve. The compliance alternative should encourage facilities with chronic deficits to reopen their uncompensated services programs and complete their obligations. This expansion would result in more uncompensated services provided to persons unable to pay. For example, based on the most recent data available at the time the NPRM was developed, hospitals which began operating fully expanded programs in fiscal year 1997 provided an average of 22 percent more uncompensated services than in the previous year under a limited program. Despite the increase in services, their average Hill-Burton deficit increased by 6 percent due to the effect of the CPI adjustment applied to large deficits. Nursing homes which began operating fully expanded programs in fiscal year 1997 provided an average of 39 percent more uncompensated services than in the previous year. Despite the increase in services, their average Hill-Burton deficit increased by 16 percent, also because of the CPI adjustment.

Thus, it was thought that the proposed rule would likely result in more facilities operating fully expanded programs, and also that more uncompensated services would be provided during their periods of obligation. The immediate value to the community of the increase in the uncompensated care services provided to eligible individuals under a fully expanded program is greater than the value of deferred services provided at some indeterminable, unspecified future date. Moreover, the new alternative implements best the intent of the 1979 regulation which set a fixed period of 20 years to fulfill a facility's obligations. This rule gives facilities which operate fully expanded programs the option of obtaining a fixed period of obligation.

As of the time of writing the proposed rules, approximately 188 hospitals nationwide could qualify for the proposed alternative once they begin to implement compliant and fully expanded uncompensated services programs. Significant is the fact that only four States have more than eight potentially qualifying facilities: New York, 32; Pennsylvania, 22; Wisconsin, 13; and Michigan, 12. Within the State of New York, 21 of the 32 facilities are the sole hospital care provider within their municipality. In Pennsylvania, this is true for 13 of the 27 facilities; in Wisconsin, 12 of the 13 facilities; and in Michigan, 10 of the 12 facilities. This means that these facilities are not meeting their uncompensated services obligations because there are not enough Hill-Burton eligible people in their communities. They are not shifting the burden of caring for the poor to other facilities since in most cases the Hill-

Burton obligated facilities are the only community providers. Further, where Hill-Burton obligated facilities are located with other providers in urban communities with large, low-income populations, in general, they have not met their obligations because: (1) Their Hill-Burton assistance was large resulting in very high annual compliance levels; (2) they sometimes implemented restricted programs; and (3) they sometimes failed to obtain eligibility documentation for uncompensated services provided to low-income persons. Most of these urban facilities would have to operate an additional 10 or more years under the alternative.

The alternative could impact as many as 121 nursing homes nationwide once they all begin to implement compliant and fully expanded uncompensated services programs. Significant is the fact that only two States, Michigan with 20 facilities and Ohio, with 15 facilities, have more than seven qualifying nursing homes. Thirty States have three or fewer facilities, with 15 of the States having no facilities. Further, the typical nursing home has 75–90 percent of its patients covered by Medicaid and Medicare, leaving few and sometimes no Hill-Burton eligible patients for credit against their obligations.

For these reasons, we conclude that where a Hill-Burton facility has a record of operating a visible, compliant, and fully expanded uncompensated services program, its uncompensated services deficit is due to a lack of community need.

In addition to the foregoing, various technical and conforming changes to the existing Subpart F were proposed. The NPRM also solicited comments on the proposed changes.

## III. Public Comment and the Department's Responses

The Department received nine comments on the proposed rule. Thirty-five health care facilities are represented by the comments. Two commenters commended the proposed rules, expressing the opinion that the new compliance alternative will allow facilities currently in deficit to complete their Hill-Burton uncompensated services obligation in a realistic way. Two commenters expressed the opinion that the Hill-Burton program is archaic and should be terminated immediately. The remaining five commenters raised specific issues regarding the details of the proposed rules. Their comments and the Department's responses thereto are summarized below.

### *1. Criteria for Certification*

Public Comment

A number of commenters questioned the requirement that, in order to qualify for full credit for past years under the new alternative, § 124.517, a facility must have been operating a fully expanded program. They felt that this requirement was unfair because the Department had never required expansion to a fully expanded program in order to be in compliance with the regulations.

Department's Response

Actually, the current regulation required facilities with deficits to take specific affirmative steps each year to make up deficits from previous years. See 42 CFR 124.503(b)(4). Thus, expansion from a limited allocation plan (limited services and/or limited financial criteria) up to and including a fully expanded plan was an option clearly available to all facilities throughout the program's history. The clear purpose of the affirmative action plan requirement was to increase the pool of eligible persons and medical services each facility offered in order for it to meet its obligation.

In some instances, facilities took no or only modest affirmative steps to address deficits. In others, they expanded their allocation plans to include the full range of services offered in the facility and considered income eligibility based on maximum financial criteria allowed under the regulation. Many of these facilities successfully completed their total obligation as a result of the expansion. Others did not, despite having implemented the broadest possible plan. The intent of the new rule is to recognize those facilities whose deficits continue in spite of having willingly implemented the broadest possible compliant program under the applicable rules. Thus, any deficit remaining clearly demonstrates a lack of community need and the facilities would be eligible for a year's credit for each year that they ran a fully expanded program.

Although those facilities with annual deficits which operated compliant but limited programs are ineligible to receive a year's credit, they do receive credit based on any actual uncompensated care provided. In addition, by expanding their allocation plans under the terms of the proposed rule now, they can establish a finite time for completion of the obligation, which, based on past performance, was not determinable.

Additionally, the Department has determined that for the first year that facilities were subject to the 1979 regulations (1980 for most facilities), any facility which operated a compliant Hill-Burton program will receive a year's credit under the new regulation, because only after completion of the first year was it possible to determine a facility's status in regard to excess/deficit. If a facility was in deficit status, then it became subject to the affirmative action plan requirement, which served as the catalyst for the facility to expand its Hill-Burton program.

According to the NPRM, a facility could receive a year's credit only where there was a fully expanded program for the entire fiscal year. Because many facilities expanded to a full program in the middle of their fiscal year, the Department has determined that a facility will receive a percentage of a year's credit for the first year in which it fully expanded its Hill-Burton program, depending on the effective date of the fully expanded program, as long as it continued its fully expanded program in the subsequent years.

### *2. Formula Pertaining to the New Compliance Alternative*

Public Comment

A number of commenters felt that the formula set forth in the Preamble was confusing, complex, and precluded the facilities from computing the dollars-to-years conversion.

Department's Response

The Department acknowledges that the formula may appear complex and that some facilities will require assistance to do the calculation. Therefore, the Department will provide each Title VI facility that is in deficit a preliminary calculation regarding the conversion of deficit dollars to years of obligation.

Some of the comments suggested a misapprehension about the intent of the formula. The idea behind the new compliance alternative, known as the unrestricted availability compliance alternative for Title VI-assisted facilities (§ 124.517), is to convert the Hill-Burton deficit of a facility operating a fully expanded Hill-Burton program from an amount of money to a number of years of obligation. The effect of this change is to establish an end-date for the Hill-Burton obligation to provide uncompensated services.

In order to make this conversion, the Department will first compute the number of years of obligation. The date required to do this differs from facility to facility, based on a 20-year period that began with the opening of a Hill-Burton-assisted facility. For example, a

facility which as of the start of its fiscal year 1980 had 7 years remaining in its 20-year obligation period, would have a total obligation period equal to 7.0 years.

Next, the Department will subtract one year from that total for each year that the facility implemented a fully expanded Hill-Burton program. If the facility implemented a fully expanded program for 4 years, it would have a balance of 3 years of obligation remaining. Next, the Department will compute partial years' credit, through use of a formula, for years that the facility earned credit but did not have a fully expanded program. The facility will receive credit expressed in time proportionate to its total outstanding obligation, after allowing credit for whole years credited in the previous step. If the above facility was determined to have a maximum remaining deficit equal to $500,000 and was credited with providing $100,000 during non-fully expanded years, it would receive additional credit expressed in time equal to 20 percent of 3 years, or 7.2 months.

Once these computations have been made, each facility under the new compliance alternative will have a specified number of years remaining to provide Hill-Burton uncompensated services. As long as the facility continues to operate a fully expanded program, the years of obligation will decline until the end-date established by the computations described above.

One commenter expressed the opinion that the Department is considering the use of a formula different from the one that appeared in the NPRM. The Department is not considering any change to the formula originally published in the NPRM except as noted above.

*3. Requirements of a Fully Expanded, Compliant Program*

Public Comment

One commenter felt that, for future reference, the requirements of a compliant, fully expanded program should be a part of the regulations.

Department's Response

The requirements of a compliant, fully expanded program have been restated in the Preamble and are also included in the final rule at § 124.517(b).

In view of the fact that the rules below relieve restrictions on facilities that apply and are certified for either the provisional component of the charitable facility compliance alternative or the new unrestricted availability compliance alternative for Title VI-assisted facilities, and impose no additional duties or obligations on other facilities, delay in the effective date of these rules is not required under 5 U.S.C. 553. For the same reasons, the Secretary hereby finds that good cause exists for not delaying the effective date of the rules below. The rules are accordingly effective upon publication.

## IV. Summary of Supporting Analyses

*Executive Order 12866*

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding unnecessary burden. Regulations which are "significant" because of cost, adverse effects on the economy, inconsistency with other agency actions, budgetary impact, or novel legal or policy issues require special analysis. The Department has determined that this rule will not have an annual effect on the economy of $100 million or more, and does not otherwise meet the definition of a "significant" rule under Executive Order 12866.

*The Regulatory Flexibility Act*

The Regulatory Flexibility Act requires that agencies analyze regulatory changes to determine whether they create a significant impact on a substantial number of small entities. As the total universe of facilities with outstanding Hill-Burton obligations is small (approximately 650 facilities) and a little over half of these are presently either without deficit or have elected to comply with their uncompensated services obligations through other compliance options, it is not anticipated that the final rule will affect a substantial number of small entities, within the meaning of the Act. Moreover, the impact of the rules should be positive, as they would lessen the burden of compliance on those facilities that would elect to utilize either of the compliance options. Accordingly, the Secretary certifies that the rules below would not create a significant impact on a substantial number of small entities.

*Paperwork Reduction Act*

The unrestricted availability compliance alternative for Title VI facilities does not contain any information collection requirements subject to OMB review under the Paperwork Reduction Act of 1995. The amendment to the charitable facility compliance alternative rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. The underlying purpose of this rule is to decrease recordkeeping, reporting, and notification burden for the charitable facilities not already certified under the alternative. New estimates for the reduction of burden have been determined. They were submitted and cleared by OMB. Facilities receiving prospective certification under the charitable facility compliance alternative will no longer be required to maintain extensive records on uncompensated services (§ 124.510(a)), but instead will have to maintain only records which document its eligibility for the compliance alternative (§ 124.510(b)). These documents are ordinarily retained by the facilities so the recordkeeping requirement imposes no additional burden. This change is expected to reduce the recordkeeping burden by 50 hours per facility per year.

Similarly, reporting burden will be reduced. Charitable facilities will be required to apply once for the certification (§ 124.516(d)), and thereafter will need only to certify their continued eligibility annually (§ 124.509(b)). Currently, facilities in deficit status under the general rule must file a report each year which documents the amount of uncompensated care provided (§ 124.509(a)). Facilities certified under the alternative will have their reporting burden reduced by 5 hours per facility in the first year, and by 10.5 hours per facility in subsequent years.

Finally, notification/disclosure burden will be eliminated, because the facilities will no longer be required to: (1) Publish a notice each year of the availability of uncompensated services (§ 124.504(a)); (2) provide individual written notices to each person seeking service in the facility (§ 124.504(c)); or (3) provide a determination of eligibility to each person applying for uncompensated service (§ 124.507). These changes are expected to reduce the notification burden by 45 hours per facility per year.

All sections of the regulations that contain reporting, recordkeeping, or notification/disclosure requirements previously have been approved by OMB under the Paperwork Reduction Act (OMB #0915–0077). The NPRM invited the public to provide comments on this information collection requirement so that the Department of Health and Human Services could:

(1) Evaluate whether the proposed collections of information are necessary for the proper performance of the

functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimates of the burdens of the collections of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility and clarity of the information to be collected; and

(4) Minimize the burden of the collections of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We received no public comments on the estimated public reporting burden.

*Unfunded Mandates Reform Act*

The final rule contains no Federal mandates for State, local, or tribal governments or the private sector.

*Executive Order 13132*

The final rule has no impact on federalism as set forth in Executive Order 13132, which became effective on November 8, 1999, replacing Executive Order 12612.

*Environmental Impact Statement*

The final rule has no impact on the quality of the human environment and, therefore, an Environmental Impact Statement is not required.

**List of Subjects in 42 CFR Part 124**

Grant programs—health, Health care, Health facilities, Loan programs—health, Low income persons.

Dated: April 12, 2001.

**Elizabeth M. Duke,**

*Acting Administrator, Health Resources and Services Administration.*

Approved: June 13, 2001.

**Tommy G. Thompson,**

*Secretary.*

For the reasons set out in the preamble, part 124, subpart F, of title 42 of the Code of Federal Regulations is amended to read as follows:

## PART 124—MEDICAL FACILITY CONSTRUCTION AND MODERNIZATION

1. Revise the authority citation for part 124 to read as follows:

**Authority:** 42 U.S.C. 216, 300r, 300s, unless otherwise noted.

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

2. Revise the first sentence of § 124.503(c)(1) to read as follows:

**§ 124.503 Compliance level.**

* * * * *

(c) * * * (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. * * *

* * * * *

3. Revise the heading and introductory text of paragraph (a) of § 124.508 to read as follows:

**§ 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 § 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:

* * * * *

4. Revise the heading of paragraph (a) and add paragraph (e) to § 124.509 to read as follows:

**§ 124.509 Reporting requirements.**

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517.* * * *

* * * * *

(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.

5. Revise the heading of paragraph (a) and the heading and the first sentence of paragraph (b) of § 124.510 to read as follows:

**§ 124.510 Record maintenance requirements.**

(a) *Facilities not certified under § 124.513, § 124.514, § 124.515, § 124.516, or § 124.517.* * * *

* * * * *

(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. * * *

* * * * *

6. Revise the first sentence of paragraph (a)(3) and paragraph (b)(1)(iii)(C) of § 124.511 to read as follows:

**§ 124.511 Investigation and determination of compliance.**

(a) * * *

(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. * * *

* * * * *

(b) * * *

(1) * * *

(iii) * * *

(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.

* * * * *

7. Revise the introductory text of paragraph (b) and paragraph (c)(1) of § 124.512 to read as follows:

**§ 124.512 Enforcement.**

* * * * *

(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:

* * * * *

(c) * * *

(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;

* * * * *

8. Revise §.124.516 to read as follows:

**§ 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 co-insurance 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 purposes 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 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.

**§ 124.517 [Redesignated as § 124.518]**

9. Redesignate § 124.517 as § 124.518 of subpart F.

10. Add a new § 124.517 to read as follows:

**§ 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 requirements 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. 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.

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