

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 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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