

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

#### 42 CFR Parts 424, 488, and 489

[CMS–2268–F]

RIN 0938–AO96

#### Establishment of Revisit User Fee Program for Medicare Survey and Certification Activities

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule.

**SUMMARY:** This final rule will establish a system of revisit user fees applicable to health care facilities that have been cited for deficiencies during initial certification, recertification, or substantiated complaint surveys and require a revisit to confirm that corrections to previously-identified deficiencies have been remedied. Consistent with the President's long-term goal to promote quality of health care and to cut the deficit in half by fiscal year (FY) 2009, the FY 2007 Department of Health and Human Services' (HHS) budget request included both new mandatory savings proposals and a requirement that user fees be applied to health care providers that have failed to comply with Federal quality of care requirements. The "Revisit User Fees" will affect only those providers or suppliers for which a revisit is required to confirm that previously-identified failures to meet federal quality of care requirements have been remedied. The fees are estimated at \$37.3 million annually and will recover the costs associated with the Medicare Survey and Certification program's revisit surveys. The fees will take effect on the date of publication of the final rule and will be in effect until the date that the continued authority provided by Congress expires. At the time of publication of this regulation the applicable date is September 30, 2007. If no legislation is enacted, the fees are not retroactive to the beginning of the fiscal year. Any provider or supplier that has a revisit survey conducted on or after the date of publication will be assessed a revisit user fee and will be notified of the assessment upon data system reconciliation which can occur following the closing of the fiscal year. The fees will be available to CMS until expended. The revisit user fee is included in the President's proposed FY 2008 budget. We note through the publication of this final rule that if

authority for the revisit user fee is continued, we will use the current fee schedule in this rule for the assessment of such fees until such time as a new fee schedule notice is proposed and published in final form.

**DATES:** *Effective Date:* These regulations are effective on September 19, 2007.

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#### SUPPLEMENTARY INFORMATION:

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##### I. Background

###### A. Overview

In the June 29, 2007 **Federal Register** (72 FR 35673), we published the proposed rule entitled, "Establishment of Revisit User Fee Program for Medicare Survey and Certification Activities" and provided for a 60 day comment period. This rule sets forth final requirements and the final Fee Schedule for providers and suppliers who require a revisit survey as a result of deficiencies cited during an initial certification, recertification, or substantiated complaint survey.

The Centers for Medicare & Medicaid Services (CMS) has in place an outcome-oriented survey process that is designed to determine whether existing Medicare-certified providers and suppliers or providers and suppliers seeking initial Medicare certification are actually meeting statutory and regulatory requirements, conditions of participation, or conditions for coverage. These health and safety requirements apply to the environments of care and the delivery of services to residents or patients served by these facilities and agencies. The Secretary of the Department of Health and Human Services ("HHS") has designated CMS to enforce the conditions of participation/coverage and other requirements with these programs. The revisit user fee will be assessed for revisits conducted in order to determine whether deficiencies cited as a result of carrying out CMS's survey process obligations have been corrected.

###### B. Requirements for Issuance of Regulations

Section 20615(b) of The Continuing Appropriations Resolution ("Continuing Resolution") budget bill passed by the Congress and signed by the President directed HHS to implement the revisit user fees in FY 2007. Section 20615(b) states as follows:

The Secretary of Health and Human Services shall charge fees necessary to cover the costs incurred under 'Department of Health and Human Services, Centers for

Medicare and Medicaid Services, Program Management' for conducting revisit surveys on health care facilities cited for deficiencies during initial certification, recertification, or substantiated complaints surveys. Notwithstanding section 3302 of title 31, United States Code, receipts from such fees shall be credited to such account as offsetting collections, to remain available until expended for conducting such surveys (*Pub. L. 110–5, H.J.Res.20, § 20615(b)(2007)*).

As directed by the Secretary, in the June 29, 2007 **Federal Register** (72 FR 35673), CMS established revisit user fees for revisit surveys and put forth in regulation the definitions, criteria for determining the fee, the fee schedule, collection of fees, reconsideration process for revisit user fees, enforcement and regulatory language addressing enrollment and billing privileges, and provider agreements. In the proposed rule, cost projections were based on FY 2006 actual data and were expected to amount to \$37.3 million on an annual basis. These calculations were included in section IV Regulatory Impact Analysis in the proposed rule (72 FR 35678).

The fees will take effect on the date of publication of the final rule and will be in effect until the date that the authority provided by the Congress expires. At the time of publication of this regulation the applicable date is September 30, 2007. As discussed thoroughly in the proposed rule, based on the Congress' knowledge of section 1864(e) of the Social Security Act and already established survey and certification activities, the unambiguous nature of section 20615(b) of the Continuing Resolution, and the principles of *lex posterior derogate legi priori* or "last-in-time" rule, the Secretary has the authority to implement this revisit user fee and establish a final fee schedule. See 72 FR 35674–35675 (discussing section 1864(e) of the Social Security Act).

##### II. Summary of the Proposed Provisions and Response to Comments

In the June 29, 2007 **Federal Register** (72 FR 35673), we published the proposed rule entitled, "Establishment of Revisit User Fee Program for Medicare Survey and Certification Activities" and provided for a 60 day comment period.

We received a total of 74 comments from various providers, suppliers, health care associations, and individual health care professionals and other individuals. The comments ranged from general support of the survey process or general opposition to the proposed provisions to very specific questions or comments regarding the proposed new revisit user fee.

Brief summaries of each proposed provision, a summary of the public comments we received and our responses to the comments are set forth below. Comments related to the paperwork burden and the impact analyses are addressed in the Collection of Information and the Regulatory Impact Analysis sections in this preamble.

#### General Comments

##### 1. Time Period for Levying Fees

*Comment:* Several commenters suggested that CMS should not allow user fees for nursing home revisits beyond the end of the fiscal year. The commenters believe that nursing homes bear the brunt of the overall survey process because surveys are conducted annually for nursing homes and as such CMS should ensure that the fee is not renewed.

*Response:* The President's HHS budget for FY 2007, as enacted by the Congress, directs the HHS Secretary to implement the revisit user fees during FY 2007. Since the provisions for the revisit user fee were put forth through the annual appropriations process, continuation of the fees under this regulation beyond September 30, 2007 will depend on Congressional renewal or extension of the time period under which fees may be assessed. While nursing homes have the most frequent surveys, they also have the largest number of revisits. Revisits in nursing homes represent the largest single source revisit costs. While there would be cost to some—but not all—nursing homes as a result of the revisit fees, nursing homes also benefit from being able to reassure prospective nursing home residents and their families that the nursing home is federally certified and that there is an objective and independent system of oversight to assure quality. The revisit survey is an essential element of that quality assurance system. We also note that the revisit fees are not restricted to nursing homes, but apply to almost all providers and suppliers that require a revisit to confirm that identified deficiencies are remedied.

##### 2. Authority to Assess a Revisit User Fee

*Comment:* A few commenters expressed concern that revisit fees would be imposed when the authority granted to levy fees expires on September 30, 2007 and that there does not appear to be legislation pending that would extend CMS' authority to impose these fees beyond FY 2007. One commenter stated that if the Congress does not extend this authority, then it

appears that this rule will be void. Another commenter disagrees with CMS interpretation of section 1864(e) of the Social Security Act (the Act) as giving HHS the "authority to assess revisit user fees." The commenter felt that clearly the inclusion and specific wording in this section within the Act indicates Congress intended that the Secretary "may not impose" any fee on any facility for any survey (revisit or otherwise) for determining compliance "with any requirement of this title."

*Response:* We are frequently expected to implement legislation that is promulgated by the Congress and therefore has the force of law, as in the passed FY 2007 appropriations bill. We strive to implement the provisions in an efficient and effective manner once it becomes law. The commenter is correct that the current authority to impose the revisit user fee expires for revisits occurring after September 30, 2007, unless otherwise authorized via legislation or through the FY 2008 appropriations bill, as examples. The revisit user fee is included in the President's proposed FY 2008 budget. We acknowledge the commenter's disagreement with the Congress' intent as it relates to authority to impose any fee based on the Social Security Act. However, as we discussed in the Proposed Rule, we believe that Congress intended to give the Secretary authority to implement this revisit user fee program when Congress enacted section 20615(b) of the Continuing Resolution.

##### 3. "Good Performers Versus Poor Performers"

*Comment:* Several commenters believed that those nursing homes considered to be providing excellent care would be required to pay a revisit user fee along with nursing homes that are considered poor performers. The commenters believe that even minor infractions uncovered during an annual survey for these higher quality nursing homes would still lead to the imposition of a revisit user fee. A commenter questioned whether or not those facilities going above and beyond to provide higher level care through higher costs of operations should be subjected to this user fee in the same manner as those facilities that are performing at the bare minimum requirements with lower costs of operations if the goal is to promote a better health care environment.

*Response:* We believe that many nursing homes will pay no revisit user fees because they consistently provide high quality care, have no deficiencies identified through the survey process, and therefore will require no revisits.

Other nursing homes may require some revisits but with minimal costs because the deficiencies are not serious, and the revisit may be accomplished through an offsite survey. We have established a much lower fee for offsite surveys since actual costs to the survey program for these revisit surveys are much less than the costs for onsite surveys, and the user fee is intended only to recoup average actual costs. We believe we have designed the user fee program to result in a positive correlation between quality of care and amount of the fees—the better the quality of care, the lower the fees. We also expect that the prospect of fees for revisits will promote greater compliance with federal quality of care requirements, thereby making for fewer revisits and fewer fees over time.

##### 4. Revisit User Fee Compared to Penalty

*Comment:* Several commenters believe the revisit user fee constitutes a penalty regardless of whether cited deficiencies are appealed and overturned. They also stated that the revisit user fee imposed additional penalties that may be assessed.

*Response:* The revisit user fee does have some similarities to a quality of care penalty in so far as the revisit user fee only applies to providers or suppliers for which deficiencies have been identified. There are differences, however, between the revisit user fee and traditional penalties. For example, a traditional penalty, such as a civil monetary penalty, is assessed according to the scope and severity of individual deficiencies that have been identified. A penalty amount would be independent of the cost for the time required by surveyors to revisit the provider in order to confirm that corrections have been made. In contrast, the revisit user fee is designed only to replace the average actual cost associated with the revisits themselves. Second, currently only nursing homes are subject to civil monetary penalties; no other Medicare-certified providers or suppliers affected by this regulation are subject to CMS CMPs for quality of care deficiencies at this time. Among nursing homes, only approximately 12 percent of nursing homes are levied a CMP in any particular year, on average. If a revisit survey is required, a user fee will be assessed; however this does not necessarily mean a CMP will be levied as well.

##### 5. Revisit User Fee Compared to Taxes

*Comment:* One commenter stated that the revisit user fee amounted to a new tax. Another commenter felt that the revisit user fee was an example of extortion and that the funding to

administer the survey process including revisits is already in place. They equated this fee to have the same effect as if the IRS was to impose a fee when the individual's tax return is flagged for an audit. A commenter felt the fee would amount to financial impropriety on the part of the government.

*Response:* We believe that the commenter's characterization of the revisit user fee as a "tax" is not accurate. Taxes are typically imposed regardless of whether the taxed parties actually use the services that the tax makes possible. Taxes must be paid regardless of the extent of government services that are accessed. In contrast, the revisit user fee will be levied only for those who fail to comply fully with their responsibilities to provide quality care and to abide by federal quality of care and related requirements under the Medicare Provider Agreement and applicable regulations and laws for providers and suppliers. Such failure obliges CMS to incur revisit survey costs that would not otherwise have been incurred. The revisit user fee amount is calibrated to match the additional resources required, on average, for the surveyors to verify compliance with known federal requirements subsequent to the provider's or supplier's initial failure to meet those requirements fully.

#### 6. Effects on Resident or Patient Care

*Comment:* Several commenters raised concern that the assessment and payment of the user fee would remove several thousand dollars per facility that otherwise would be available for resident care. Another commenter felt the ethics of this proposal would adversely affect the citizens of a State. The commenter felt that the revisit user fee was unfair. Other commenters stated, in various ways, that the revisit user fee would remove valuable resources that would otherwise be expended for patient and employee resources. They felt that a direct drawdown from funds used for patient care would occur, resulting in no improvement to the quality of resident care. Finally, they felt that there would be a direct adverse fiscal impact on smaller more financially challenged facilities.

*Response:* CMS believes the providers and suppliers are the controlling agents in managing the quality of care of services provided in their healthcare facilities. Providers and suppliers may avoid revisit fees by ensuring sustained compliance with federal quality of care requirements. The revisit user fees simply compensate for the costs of confirming that previously-identified problems have been remedied. The

certainty that a revisit will occur is a substantial incentive for a provider to make the necessary corrections; therefore, we believe that this quality assurance function will improve care and safety for Medicare beneficiaries. In addition, we believe the imposition of revisit user fees will likely encourage a sustained commitment to management systems that improve quality of care provided to all clients served by the provider. CMS does not believe that the revisit user fee should harm quality of care provided, but can instead become a valuable, additional incentive to encourage providers and suppliers to commit to sustained compliance with federal quality of care requirements. The quality of care message is that providers and suppliers will have no user fees when quality of care meets the appropriate federal standards. To the extent that there are deficiencies, providers and suppliers will have only small fees to the extent that the deficiencies are not serious or widespread. If quality problems do occur, providers and suppliers will have greater incentives to ensure that quality lapses are corrected more quickly than in the past, since the revisit fees will be less if only one revisit is required.

#### 7. State Practices and Incentives for Revisits

*Comment:* Several commenters expressed a concern that State survey teams would be instructed to find more violations if a revisit user fee were in place, thus increasing the number of revisit surveys. One commenter also raised the concern that the facility will have to pay a revisit user fee for a revisit survey although the State may not consider the deficiency severe. Another commenter raised concern that there would be tremendous potential for abuse, that surveyors lacked experience and that there existed too much financial control of the facilities in the hand of the state surveyors. This commenter also expressed concern as to whether there would be adequate monitoring of State agencies for potential abuse of this program. Two commenters believed the fee would increase the number of revisits currently being done, putting an extra burden on staff as well as required additional time for State surveyors. One commenter felt that the nursing home revisits would increase to 100 percent because of what they consider a financial incentive.

*Response:* We agree that any potential conflict of interest, and any appearance of conflict of interest, must be addressed in the design and operation of any user fee program. A number of safeguards will prevent any such potential conflict

from becoming a serious reality. First, the revisit user fees will be collected nationally by CMS through a contractor rather than by individual States. CMS makes allocations to States based on the effects of inflation and on overall survey and certification workload and performance for all survey and certification functions, with revisits comprising just one of many functions. The national survey and certification budget may not exceed the level established by Congress, regardless of the level of revisit fee collections. Second, all States must conduct revisits according to policies and procedures established by CMS. Those policies and procedures are publicly available in CMS' State Operations Manual (SOM) and in numbered Survey & Certifications policy memoranda published on the CMS Web site. Such policies and procedures define the circumstances under which revisit surveys, both onsite and offsite, occur and when they do not occur. CMS Regional Offices monitor State implementation of the policies and procedures. We intend to increase CMS monitoring for revisits. Third, States incur substantial costs in order to conduct revisits. Such costs are not lightly undertaken, since there are formidable natural and governmental constraints on a State survey agency's ability to make use of any added funds that might conceivably become available even if there were a direct fiscal connection between revisits and the amount of money the State survey agency were to receive. The single largest cost to a State survey agency, for example, is personnel. The ability of a State survey agency to hire new staff (even when new revenue becomes available) is either very limited or there is a long delay between the availability of such funds and the hiring of a surveyor. Once hired, the surveyor must typically undergo about six months of training and observing before being entrusted to conduct surveys. These constraints make it unlikely that a State survey agency would incur the upfront staffing costs of conducting revisits that were not required, or would seek to identify more deficiencies simply to justify a revisit and hope that at some vague future date the added costs might be recognized by CMS. To the extent that the revisit user fee does create any type of new incentive, we expect that the main incentive will be for providers and suppliers to maintain compliance with federal quality of care and safety requirements, since such compliance offers a clear pathway to the avoidance of revisit fees.

*Comment:* One commenter stated that the proposed rule would increase fees for facilities that had follow-up for routine licensure/certification surveys as well as complaint visits.

*Response:* Revisit user fees will apply only to surveys that occur after an initial certification, recertification, or substantiated complaint survey has identified deficiencies. State licensure issues that a State survey agency might address during a survey or a revisit survey are separate activities not connected with the assessment of a revisit user fee. Surveyor time spent on State-only issues must also be cost-accounted for by State survey agencies to ensure that such costs are not billed to the federal government. Thus, a survey or revisit survey based solely on State licensure requirements would not create the assessment of a revisit user fee. Only the need to conduct revisit surveys regarding Federal conditions of participation, requirements, or conditions for coverage would trigger a revisit user fee.

*Comment:* One commenter observed that State and federal regulations require nursing facilities to report allegations of abuse and other issues to the State survey agency. The commenter expressed concern that such mandatory reports will result in a visit from the Survey Agency inspectors, usually without any finding of regulatory deficiencies. The financial impact of the proposal could be very burdensome for many nursing facilities.

*Response:* An initial visit to investigate a complaint, such as the allegation of abuse and or neglect mentioned by the commenter would not trigger a revisit user fee. A revisit would be required only if a deficiency is identified as a result of that complaint investigation. The user fee would not apply to the initial complaint investigation; it would apply only to the revisit once the provider has alleged to the State survey agency that it has addressed the deficiency identified in the original complaint investigation. Complaint investigations that find no deficiencies will not require any revisits and will therefore not occasion any revisit fees.

#### 8. Revenue Seeking—Government Responsible for Funding Survey Process

*Comments:* Several commenters felt that this proposed rule and the assessment of revisit user fees was a revenue seeking mechanism, that it was a way to fund and pay for the survey process. Many of these same commenters felt that the obligation of the survey process and the conducting of revisit surveys was that of the Federal

government, and or the State Health Departments. The government has mandated these surveys and as such the quality assurance checks are its obligation. One commenter felt that the Federal government's role is to raise these funds, as been often done through Federal taxes, although not advocating a Federal tax increase, it is through these like efforts the commenter suggested that funds should be derived to pay for the survey process.

*Response:* The revisit user fee is designed simply to pay for actual costs of conducting revisits, on average, rather than as a revenue generating instrument that might be unconnected with the government activity for which the revisit user fee is assessed. In addition, the revisit user fees offer the ancillary benefit of encouraging providers and suppliers to commit to sustained compliance with Federal quality of care requirements and ensure that quality lapses are remedied quickly.

#### 9. Creating Positive Incentives

*Comment:* Although some commenters felt the revisit user fee was punitive in nature and not proactive, several commenters did support added incentives to increase patient and resident safety, quality of care, and compliance to standards. A couple of commenters went on to state that a positive incentive would serve to strengthen the relationship between regulators and providers and would establish CMS as a partner rather than an adversary of the long-term care community. A few commenters indicated strong support of the Medicare survey process as one method to assure only providers and suppliers that offer high quality services participate in the Medicare program. One commenter went as far as offering three goals for which the collected user fees should be directed, which included improving consistency of the survey process, ensuring complete, provider-specific training for surveyors, and improving communication between State survey agencies and the provider community on survey rules and expectations. This commenter went on to state that fees derived for these survey program improvements should not be used to merely supplant the normal funding stream but dedicated to specific programs.

*Response:* The intent of the revisit user fee program is to recover the costs associated with conducting follow-up visits for deficiencies cited during initial certification, recertification, and substantiated complaint surveys. Although the commenter offers three additional goals for the collected revisit

user fee, we believe that those admirable goals go beyond Congress' intended purpose of the revisit user fee program.

#### Part 424—Conditions for Medicare Payment

##### Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

###### Section 424.535 Revocation of Enrollment and Billing Privileges in the Medicare Program

We proposed to amend § 424.535(a)(1) by adding a new sentence to the criteria for which a provider or supplier may be determined not in compliance and for which we may revoke enrollment and billing privileges in the Medicare program. We proposed to add that the provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter. The paragraph will continue to read that all providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges occurs.

*Comment:* Some commenters tied in the discussion of revocation of billing and the termination for nonpayment as proposed in § 488.30(f) and § 489.53(a)(16). One commenter felt that termination for nonpayment within 30 days is power disproportionate to the offense and is unrelated to quality of care and safety issues. Another commenter felt that this provision is reason not to participate in Medicare, or to care for Medicare patients.

*Response:* While we proposed that a provider or supplier may also be determined not to be in compliance if a revisit user fee payment has not been received within 30 calendar days after receipt of the notice that payment is due, we also state at § 424.535(a)(1) that all providers and suppliers are granted an opportunity to correct the deficient payment compliance before a final determination is made to revoke billing privileges. We further note that a payment-due notice from CMS is preceded by a survey or complaint investigation that has found deficiencies, a correction period afforded to the provider or supplier, a revisit to confirm compliance, then a later issuance of the payment-due notice, followed by the formal 30-day advance notice to the provider. As soon as a revisit occurs, each provider or supplier will know that a revisit user fee will follow at a later date, will know the amount of the fee due from the fee schedule published in this rule, and will know that the payment will be due

within 30 calendar days. While the rule specifies that enforcement action may occur if the bill has not been paid within 30 calendar days, the total amount of planning time available to the provider or supplier will have totaled much more than the 30 calendar day period before any enforcement action may occur. Finally, the revocation of billing and enrollment privileges is not an immediate action upon the failure of a provider or supplier to remit the assessed revisit user fee. In this final rule we therefore retain the time frames for which action will occur regarding this process and retain the amended language to § 424.535(a)(1) as final.

## Part 488—Survey, Certification, and Enforcement

### Subpart A—General Provisions

#### Section 488.30 Revisit User Fee for Revisit Surveys

We proposed a new § 488.30 which set forth proposed regulations that identifies the circumstances under which providers or suppliers be assessed a user fee for revisit surveys connected with deficiencies identified during surveys for initial certification, recertification, or substantiated complaints. This proposed paragraph identifies the assessment of fees, criteria for which the proposed fee schedule will be based, and collection of fees.

#### Section 488.30(a)—Definitions

We proposed in § 488.30(a) to define terms associated with this paragraph. Those terms included: “certification,” “complaint surveys,” “substantiated complaint survey,” “provider of services,” “provider,” “supplier,” and “revisit survey.” Many of the comments received for § 488.30(a) dealt less with the wording in the definitions and more with the survey and certification activities and its process.

#### Certification (Initial or Recertification)

We proposed that “certification” (both initial and recertification) would include those activities as defined in § 488.1. “Certification” as currently defined in § 488.1 is a “recommendation made by the State survey agency on the compliance of providers and suppliers with the conditions of participation, requirements (SNFs and NFs), and conditions for coverage.”

*Comment:* One commenter proposed that home health agencies and hospice facilities be removed from initial certifications since it can take 2 or more years to get initial certifications. Another commenter proposed that the revisit user fee should be expanded to include initial surveys of ESRD facilities

to allow more timely surveys that now are delayed due to CMS budget, staff shortages, and other priorities.

*Response:* Both commenters are referring to the issue of initial certification surveys conducted for new providers or suppliers, rather than the revisit surveys themselves.

While we appreciate the suggestion from one commenter that CMS charge a fee for initial surveys so as to eliminate the current backlog of unsurveyed and uncertified potential Medicare providers, we are neither authorized by Congress nor prepared to charge such fees at this time.

We also do not accept the suggestion from the other commenter that home health agencies and hospices simply be exempt from initial certification due to the survey backlog. We are not authorized to make such exemption. We also believe an exemption would be inadvisable, as it would permit those providers to begin to serve Medicare beneficiaries without any assurance that they meet quality of care and safety requirements. The proliferation of new home health and hospices in a few States have also given rise to considerable concerns of fraud, a concern that CMS is responding to through various anti-fraud initiatives recently announced by the Secretary.

We do expect that the revisit user fee will indirectly help to resolve the problem of surveying and certifying new providers. Revisit costs represent a minority but still substantial portion of overall survey and certification expenses. By defraying such costs through the user fees, the States will then be in a better position to conduct tier III and tier IV priority work, and will be able to conduct more initial surveys than they have been able to conduct recently.

While we appreciate the comments, to adhere to the Congress intent within the Continuing Resolution, we will not assess a fee for initial certification, nor at this time can we remove providers or suppliers based on when initial certifications are conducted. We will retain the proposed definition of “certification” as final.

#### “Complaint Surveys”

We proposed that complaint surveys are those surveys conducted on the basis of a “substantial allegation of noncompliance,” as defined in § 488.1. The term “substantial allegation of noncompliance” means:

A complaint from any of a variety of sources (including complaints submitted in person, by telephone, through written correspondence, or in newspaper or magazine articles) that if substantiated,

would affect the health and safety of patients and raises doubts as to a provider’s or supplier’s noncompliance with any Medicare condition. (42 CFR § 488.1)

We further noted that the Continuing Resolution included the term “substantiated complaints surveys.” We proposed that “substantiated complaint survey” means a complaint survey that results in the proof or finding of noncompliance at the time of the survey, a finding that noncompliance was proven to exist, but was corrected prior to the survey, and includes any deficiency that is cited during a complaint survey, whether or not the deficiency was the original subject of the substantial allegation of noncompliance.

We proposed that a user fee would be assessed for revisit surveys conducted to evaluate the extent to which deficiencies identified during a substantiated complaint survey have been corrected.

*Comment:* Commenters requested clarification on the term “substantial allegation of noncompliance,” and felt that the definition as a basis for the revisit fee is vague and open-ended.

*Response:* CMS proposed the definition for “complaint surveys” to mean those surveys conducted on the basis of a substantial allegation of noncompliance, as defined in § 488.1. “Substantial allegation of noncompliance” has been the term used in current survey, certification, and enforcement procedures and as such we intended to maintain a level of consistency by utilizing this definition as a means to define “complaint surveys.” It is this process that generates the action for which an investigation into the complaint should occur. It is the substantiation of this complaint survey that will determine if a revisit survey should be conducted and as a result a revisit user fee should be assessed. As we provided in the discussion of the proposed rule “substantiated complaint survey” means a complaint survey that results in (1) the proof or finding of noncompliance at the time of the survey, (2) a finding that noncompliance was proven to exist, but was corrected prior to the survey, and (3) includes any deficiency that is cited during a complaint survey, whether or not the deficiency was the original subject of the substantial allegation of noncompliance. If any of these 3 situations are determined and a revisit is required as a result of the situation, then a revisit user fee will be assessed. It will not simply be based on whether the complaint was substantiated. A complaint may be substantiated without

being determined to be non-compliant with the regulations. The substantiation of a complaint is a separate issue from the determination of compliance with the regulations and thus the triggering of a revisit user fee.

*Comment:* One commenter contends that accepting complaints from a variety of sources is overly broad and permits the process to go forward at great length. Another commenter felt that there is nothing to prevent disgruntled employees from submitting complaints anonymously, especially once they learn that the user fee will punish the facility. Commenters felt that this provides incentive for surveyors to substantiate the complaint that triggered the revisit or substantiate another deficiency.

*Response:* We do not expect that either the quantity of complaints received or the source of the complaints will affect revisit user fees to any measurable extent. The revisit user fee does not apply to any complaint investigation. Only complaints which have been substantiated as showing non-compliance with Federal requirements will result in citation of a deficiency. Only those deficiencies that require a revisit survey will then trigger a revisit user fee. When multiple complaints are received near the same point in time, State survey agencies typically bundle those together in one complaint investigation, this investigation is followed by a revisit survey only if one or more of the complaints is substantiated and the agency finds noncompliance to such an extent that a revisit is called for according to CMS policy. Finally, the volume of complaints reaching CMS are to some extent affected by the extent that the provider or supplier has an effective system of inviting complaints internally, and responding to complaints effectively such that beneficiaries or their families feel that there is less need to file complaints with CMS or any external party. We believe that beneficiary complaints represent a very important source of feedback for providers, suppliers, CMS and States. We hope such feedback can be effectively used by us and others to identify areas of health care that merit serious attention.

*Comment:* One commenter disagreed that a "substantiated complaint survey" can cite any deficiency regardless of whether that deficiency was the original subject of the complaint. Two commenters raised concerns that a revisit user fee will be imposed even in cases where a "substantiated complaint" is corrected prior to the survey or that CMS would require a

revisit user fee in this instance and this would discourage a facility's internal quality assurance. A commenter raised the questions as to whether a substantiated complaint included condition and standard levels or just condition level. This commenter proposes that it just include condition level since those levels result in non-certification or decertification.

*Response:* CMS published condition of participation, condition for coverage and other regulatory requirements typically take the form of specific standards, with multiple standards related to a common topic comprising a broader "condition." Revisit surveys are almost always required for condition-level deficiencies and are also often required for standard-level deficiencies, depending on the extent and seriousness of the noncompliance identified. As we provided in the discussion of the proposed rule, "substantiated complaint survey" means a complaint survey that results in (1) the proof or finding of noncompliance at the time of the survey, (2) a finding that noncompliance was proven to exist, but was corrected prior to the survey, and (3) includes any deficiency that is cited during a complaint survey, whether or not the deficiency was the original subject of the substantial allegation of noncompliance. If any of these 3 situations are determined and a revisit is required as a result of the situation then a revisit user fee is assessed.

Although we disagree in part with the commenter who indicated that any deficiency can not be cited during a complaint survey, we reiterate and clarify that under our current policy for conducting complaint surveys, we do require that if a State surveyor in the course of conducting the complaint survey observes a situation that warrants further investigation, that the State must seek input from the CMS regional office to request permission to further pursue this additional situation. See U.S. Centers for Medicare & Medicaid Services. *State Operations Manual*, "Complaint Procedures." ONLINE. 2006. CMS. Available: <http://www.cms.hhs.gov/manuals/downloads/som107c05.pdf> ("SOM-Complaint").

With regard to the two commenters' concern that a finding that noncompliance was proven to exist, but was corrected prior to the survey, this situation alone would not trigger a revisit user fee. In addition, because a substantiated complaint survey can include the above criteria we do not believe at this time that we should make a distinction between a condition level deficiency and a standard level

deficiency. As a continued part of the survey and certification process a complaint may be substantiated without being determined to be non-compliant with the regulations. The substantiation of a complaint is a separate issue from the determination of compliance with the regulations and thus the triggering of a revisit user fee.

We appreciate the comments, however to adhere to consistency across current survey and certification policy, we will retain the definition of "complaint surveys" to mean those surveys conducted as the basis of a substantial allegation of noncompliance, as defined in § 488.1 as final.

*"Provider of Services, Provider, or Supplier"*

We proposed to retain the terms "provider of services," "provider," or "supplier" as defined in § 488.1. We proposed that all "provider of services," "providers," or "suppliers," as defined in § 488.1, will be subject to user fees, unless otherwise exempted through the final rule. We proposed that a "provider of services" or "provider" that may be assessed a user fee, as it applies in this proposed rule, includes a hospital, critical access hospital, skilled nursing facility, dually-participating nursing facility ("SNF/NF"), home health agency ("HHA"), and hospice. Transplant centers would also be subject to user fees and have been defined in § 482.70 of this chapter. We proposed that "providers of services" or "providers" that will not be assessed a revisit user fee as defined in the proposed rule to be comprehensive outpatient rehabilitation facilities, transplant centers, and providers of outpatient physical therapy or speech pathology services. These providers are excluded from this rule because they are not subject to a routine survey process as are other service providers. We stated that Medicaid-only "providers of services" or "providers" will not be assessed a user fee.

We proposed a "supplier" that may be assessed a user fee, as it applies in the proposed rule includes an end-stage renal disease center, a rural health clinic ("RHC"), and an ambulatory surgical center ("ASC"). ASCs must have an agreement with CMS to participate in Medicare and must meet conditions for coverage as defined in Part 416 of this chapter.

"Suppliers" that would not be assessed a user fee under the proposed rule are independent laboratories, portable x-ray centers, physical therapists in independent practice, Federally Qualified Health Centers (FQHCs), and chiropractors. These

suppliers are excluded because they are not subject to a routine survey process as are other suppliers. We stated that Medicaid-only “suppliers” will not be assessed a user fee.

The proposed rule would not interfere with user fees associated with clinical laboratories as established by the Congress, which passed the Clinical Laboratory Improvement Amendments (CLIA) in 1988 and established that outpatient clinical laboratory services are paid based on a fee schedule in accordance with section 1833(h) of the Act.

We received several comments regarding our definition of “provider of services,” “provider,” or “supplier” and we have included them below.

*Comment:* One commenter indicated that Chiropractors status among the Allied Health Care professions remains in dispute, this commenter contends that Chiropractors should be excluded from any Medicare provider list.

*Response:* Our current regulations found in § 488.1 include Chiropractors as identified as a supplier. This particular definition section also has extensive implications in various parts of the Medicare and Medicaid program and although we appreciate the commenter’s concern, we do not propose to remove chiropractors from the definition of supplier. We do reiterate that Chiropractors are not subject to the revisit user fees.

*Comment:* One commenter believed that the implementation of this rule should not coincide with the publication of the final rule for ESRD conditions of coverage. This commenter felt that revisits and assignment of fees could very well be excessive during the “learning curve” of the new regulation; if CMS has such discretion the commenter suggests that this final rule should state that revisit user fees for ESRD facilities will not apply for the first 12 months of implementation of new conditions for coverage.

*Response:* The commenter is referring to the future publication of the final CMS rule revising the Conditions of Coverage for end stage renal disease facilities (ESRD). New rules or substantial revisions of new rules are typically promulgated with future effective dates. Considerable educational communications usually precede the effective date, during which providers or suppliers have an opportunity to become familiar with the rule and make necessary changes before the survey process holds them accountable. Currently, ESRD surveys are conducted about once every three to five years. We therefore believe that there will be reasonable opportunities

for providers to adjust to the new rules before they are affected by surveys and the later revisits that might follow some surveys. Finally, although we appreciate the commenter’s suggestion, we do not have the discretion at this time to exclude ESRD facilities from this final rule. ESRD facilities and revisits costs were included within the President’s budget projections and mandated by the Congress.

*Comment:* One commenter expressed concern that religious nonmedical health care institutions (RHNCIs) would be subject to the revisit user fees.

*Response:* We appreciate the comment received. We inadvertently did not include religious nonmedical health care institutions (RHNCIs) in the definitions. RHNCIs should have been included, as they are subject to the survey and certification process. To adhere to the intent of the Congress and maintain consistency of definitions across Medicare and Medicaid programs, we will retain the definitions as proposed with the exception that we will include RHNCIs in the definition. However, in the fee schedule in this final rule we exempt them from the user fee program due to the very small number of such facilities and their relatively unusual nature. Any change to the exemption status would be preceded by publication of a **Federal Register** notice. The final definition of “provider of services,” “provider,” or “supplier” will read “Provider of services, provider, or supplier” as defined in § 488.1, and ambulatory surgical centers, transplant centers, and religious nonmedical health care institutions subject to § 416.2, § 482.70, and § 403.702 of this chapter, respectively, will be subject to user fees unless otherwise exempted.

#### “Revisit Survey”

In the Proposed Rule CMS defined the term “revisit survey” to mean a survey performed with respect to a provider or supplier cited for deficiencies during an initial certification, recertification, or substantiated complaint survey and which is designed to evaluate the extent to which previously cited deficiencies have been corrected. We further proposed that for purpose of this rule revisit surveys include both offsite and onsite. We also reiterated that regulations established in § 488.26 of this same part provided regulatory requirements for conditions of participation, conditions for coverage, or other regulatory requirements. Specifically § 488.26 of this part states that the compliance determination is made by the State survey agency and includes a survey process that assesses

compliance with Federal health, safety, and quality standards.

We received only a few comments regarding the term “revisit surveys” and received the majority of comments under this section reflecting commenters concern regarding the survey process and the manner in which revisit user fees will be assessed.

#### 1. “Revisit Survey” Term

*Comment:* Several commenters requested that we redefine the term “revisit survey” so that the definition does not include desk reviews or offsite surveys, that the offsite (desk) reviews be defined, that fees only be imposed if the survey is done in accordance with already established policies per provider type, that the definition include criteria about when onsite revisits are required, and that we limit the fees to “onsite revisit surveys.”

*Response:* We included offsite revisit surveys (desk reviews) because we wished to retain the option of the offsite revisit surveys where warranted, since the cost to providers and suppliers under the revisit fee program will be substantially less than for onsite revisit surveys. The function of onsite and offsite (desk review) revisit surveys is the same. We interpret both types to constitute revisits within the meaning intended by Congress. The Continuing Resolution requires fees to be assessed that are necessary to cover the costs incurred for conducting revisit surveys on health care facilities cited for deficiencies found during initial certification, recertification, or substantiated complaint surveys. As we observed, we do not interpret this to mean onsite revisit surveys only. Within the current survey process itself there are distinctions made for when an onsite or offsite revisit survey should occur and distinctions are made by provider and supplier type. See U.S. Centers for Medicare & Medicaid Services. State Operations Manual, “Survey and Enforcement Process for Skilled Nursing Facilities and Nursing Facilities,” Online. 2004. CMS. Available: <http://www.cms.hhs.gov/manuals/downloads/som107c07.pdf>, and also “Additional Program Activities,” Online. 2007. CMS. Available: <http://www.cms.hhs.gov/manuals/downloads/som107c03.pdf>.

We disagree that revisit surveys should only be those that were conducted onsite, as there are situations in which offsite reviews are required to verify that the contents of the plan of correction or the corrective action took place. We do, however, agree that a review of a plan of correction that does not require verification beyond the plan

of correction document itself would not constitute an offsite revisit survey (as defined here), and thus the provider or supplier would not be assessed a revisit user fee in such a circumstance. A provider or supplier will be assessed a revisit user fee for an offsite revisit survey if the deficiency or deficiencies cited are of a nature that the content of the plan of correction and the statements made by the provider or supplier require verification and offsite follow-up to ensure that the corrective action has brought the provider back into compliance with federal requirements.

We appreciate the comments received; however on the term "revisit survey," based on our discussion we will retain the proposed definition of "revisit survey" as final.

## 2. Survey Process

CMS discussed the current revisit policy and survey and certification process already established for all providers and suppliers. We identified current policy for skilled nursing facilities and dually-participating nursing facilities, performed at the discretion of CMS or the State. This revisit policy indicates circumstances for which onsite revisits must occur for certifying compliance and circumstances when onsite revisits are discretionary. Likewise, CMS generally permits only two revisits for hospitals, home health agencies, hospices, ambulatory surgical centers, rural health clinics, and end-stage renal disease centers. Of these two revisits permitted by CMS, one revisit should occur within 45 calendar days of the initial certification, recertification, or substantiated complaint survey, and one revisit subject to CMS approval, between the 46th and 90th calendar days. See 72 FR 35676 (discussing revisit policy, including discussion on revisits related to Immediate Jeopardy).

### 2A. Survey Process: Skilled Nursing Facilities and Dually-Participating Nursing Facilities

*Comment:* Several commenters contended that the survey process is inconsistent and subjective, and proposed that the revisit user fees be postponed until these process issues are resolved. Another commenter felt that revisit user fees represent punishment, especially when deficiencies are erroneously cited. Two commenters requested assurances that only legitimate deficiencies will be cited, that unnecessary revisits will not be conducted, and that revisits will not be conducted solely for the purpose of collecting user fees. One commenter felt

that the proposed rule will complicate the subjectivity and variability that will always be part of the survey process. Another commenter indicated that the survey process is broken and subjective, and as such, fees for revisits would be unfair until those problems are resolved.

*Response:* CMS continuously works with States to ensure that surveys are applied as consistently as possible. CMS also operates a national internal consistency program in which validation surveys are conducted by Federal surveyors to promote optimum consistency. For example, Federal surveyors conduct validation surveys on a 5% sample of nursing home surveys to check the accuracy and adequacy of State surveys. CMS then works with the States to adjust for any significant disparities. The issue of consistency is also monitored as part of CMS's review of State performance. Because no system is perfect, nursing homes have an opportunity to request review of any cited deficiency through a structured informal dispute resolution process. CMS takes the issue of consistency seriously, and we continue to develop additional methods to analyze and address consistency issues, one example is the new Quality Indicator Survey (QIS) process that has been pilot-tested in five States. The QIS process utilizes customized software and is designed as a staged process for use by surveyors to systematically review requirements and objectively investigate all triggered regulatory areas in an effort to meet several objectives, one of which is to improve consistency and accuracy of quality of care and quality of life problem identification. We believe that the revisit user fee will help address those limitations and make more feasible a number of additional consistency improvements that are underway.

*Comment:* One commenter feared that there are no constraints to prevent a surveyor from citing an already corrected problem in order to trigger a revisit. One commenter believed that the survey process is already stressful for facility staff and this will only be made worse for employees who fear any mistake could trigger a revisit and its associated fee.

*Response:* If a problem has already been corrected at the time of a standard survey or complaint investigation, the survey itself can confirm that the correction has brought the provider or supplier back into compliance with federal requirements and the surveyor would document such a determination. In such a case no revisit would be required unless the correction failed to assure compliance. We appreciate that

the survey process can be inherently stressful for employees. We do not believe, however, that the amount of the revisit fee is so much as to add measurably to the pre-existing stress level for employees. The cost of a revisit fee can be compared favorably to the larger cost to beneficiaries from poor quality of care, or to the larger financial cost to providers from serious non-compliance with federal requirements, such as civil monetary penalties or termination of the provider agreement. Only in the case of multiple revisits would we expect the cumulative cost of revisits fees to become a significant expense for a particular provider. A large number of revisits would occur when there is a persistent pattern of poor quality and documented inability of a provider or supplier to sustain compliance with federal requirements. Such providers face more serious consequences than revisit user fees. We believe that the plain language of the Continuing Resolution mandates that a fee be collected whenever a revisit occurs as a result of a deficiency found during initial certification, recertification, or substantiated complaint surveys. Documentation requirements supporting deficiency citations are not being diminished, eliminated or otherwise changed by this proposed rule to create the scenario raised by the commenter.

*Comment:* One commenter proposed that onsite revisits be discretionary for single "G" level deficiencies. Another commenter indicated that it is unclear what level deficiency would necessitate a revisit. A few commenters believed that oversight of correction of some deficiencies could be done offsite and requested clarification about when onsite revisits are required.

*Response:* Our current policy requires onsite revisits for condition level citations. The current policy governing revisit surveys is described in our online state operations manual. We will, however, consider policy issues raised by several of the commenters for future reconsideration. Some professional discretion on the part of State survey agencies will always be required. CMS provides review and oversight of State survey agencies through the CMS regional offices. Our internal quality assurance system provides for regional office up-front input or subsequent review when there is concern regarding whether the revisit survey should be conducted onsite or offsite. However we have always maintained that a condition level citation requires an onsite revisit survey. "G" level deficiencies in nursing homes are serious and are cited only when one or more nursing home



residents have been harmed. We will continue to conduct revisits in such circumstances.

2B. Survey Process: Hospitals, Home Health Agencies, Hospices, Ambulatory Surgical Centers, Rural Health Clinics, and End-Stage Renal Disease Centers

*Comment:* One commenter felt that although survey teams work off the same worksheets, there is variation in how different survey teams assess similar situations. Therefore, the commenter felt that requiring a "revisit" fee for all resurveys (either onsite or offsite) will increase the number of times that home health agencies will contest the survey findings, which then they may enter into an informal dispute resolution process not only to avoid the revisit fee but also to respond to the issue of survey variation.

*Response:* CMS continuously works with States to ensure that surveys are as consistently applied as possible. CMS also operates a national internal consistency program in which validation surveys are conducted by Federal surveyors to promote optimum consistency. It is possible that the revisit user fees may have the ancillary effect of increasing the extent to which providers or suppliers dispute the findings of surveys or complaint investigations. We believe this may occur whether the revisits are offsite or onsite. We will monitor the effect of the revisit fees to determine if any future adjustments are advisable.

*Comment:* One commenter requested clarification on whether user fees will be imposed on accredited providers or suppliers for a revisit following a sample validation survey.

*Response:* We will not charge a fee for a validation survey of a provider or supplier that has been duly accredited by a CMS-approved accrediting organization and deemed to meet Medicare requirements. While we believe that a revisit fee pursuant to a validation survey has basis, it is absent in the language of the Continuing Resolution. We would view this as similar to a revisit survey conducted for a non-accredited provider; we did not however specify such a charge in the proposed rule. We will therefore not charge a revisit user fee in this final rule for a revisit that follows a validation survey, provided that the deemed status of the provider or supplier has not been removed by CMS. However, any survey, including a validation survey, that finds noncompliance with a Condition (compared to just a Standard), typically requires removal of deemed status and a full survey of a provider. When an accredited facility is found not to be in

substantial compliance with the Medicare Conditions of Participation or Conditions for Coverage, it must remain under the jurisdiction of the State Survey Agency until the State Survey Agency verifies through revisits that the facility has corrected its deficiencies and demonstrated substantial compliance. We believe in this case, the removal of deemed status that initiated with a validation survey, that then remains under the jurisdiction of the State survey agency is equivalent to any other provider or supplier seeking recertification. In this case a provider or supplier cited for a deficiency during a recertification survey that requires a revisit survey would be assessed a revisit user fee.

*Comment:* One commenter requested clarification as to whether a full survey following a substantiated complaint survey in a deemed provider or supplier is a revisit as defined in proposed § 488.30(a).

*Response:* A full survey that is conducted pursuant to a complaint investigation of an accredited facility that has found condition-level noncompliance is viewed as a revisit for the purposes of the revisit fee. As discussed in the response above, noncompliance with a Federal condition typically requires a removal of deemed status and a full survey of a provider. The purpose of this full survey is two-fold: To verify correction of the condition-level deficiencies identified on the complaint investigation, and also to confirm that the facility is in substantial compliance with all of the pertinent conditions for participation before the State survey agency returns jurisdiction over the facility to the accreditation organization. Thus we believe the activities of the survey fall within the purposes of a revisit survey.

We appreciate all the comments received regarding our current survey process for all providers and suppliers. CMS will maintain the current policy process for the immediate future. We will take all of these comments under consideration as we continue to work with States and our national consistency program to provide continued oversight and regulatory compliance guidance.

#### *Section 488.30(b)—Criteria for Determining the Fee*

We proposed in § 488.30(b) to provide the criteria for determining the user fee. We proposed that for initial implementation of revisit user fees, we will use the criteria in proposed § 488.30(b)(1)(i) and (ii): That a provider or supplier will be assessed a revisit user fee based on the average cost per revisit survey per provider or supplier

type and the type of the revisit survey (onsite or offsite). If costs change significantly in any future period for which authority for the revisit user fee exists, we would publish a **Federal Register** notice providing a revised fee schedule to the extent that fees may be affected.

We also proposed that exceptions to the assessment of a revisit user fee will be identified based on the type of visit conducted. For example, we proposed that neither a provider nor a supplier will be assessed a fee if the visit is considered a "State monitoring visit" unless the visit also meets the definition of a revisit, if the visit is to confirm Medicare provider or supplier compliance with Life Safety Code (LSC) requirements, if the visit is to conduct a Federal Monitoring Survey, such as a Federal look-behind survey. See 72 FR 35677 (discussing "state monitoring visit," LSC, and Federal Monitoring Surveys).

We also proposed in § 488.30(b)(1)(iii) through (b)(1)(v) that CMS may adjust revisit user fees to account for the provider or supplier's size, typically determined by capacity (such as the number of beds), the number of follow-up revisits resulting from uncorrected deficiencies, and/or the seriousness and number of deficiencies (such as the scope and severity of cited deficiencies and the number of deficiencies cited at each scope and severity level), as these criteria pertain to particular provider types. Variance in provider/supplier size, the number of follow-up revisits, and the type and number of deficiencies cited may have an impact on the survey hours needed for a revisit. We also proposed in § 488.30(b)(2) that CMS may adjust the fees to account for any regional differences in cost.

We received a variety of comments for this section, the majority of which discussed quality of care and the concern that the user fee might cause adverse incentives. We summarized all of these comments and responded to them under the general comments section of this final rule. The comments discussing the specific criteria proposed in § 488.30(b) are provided below.

*Comment:* A few commenters stated that additional information was needed about how the various factors (for example, a provider's size, number of revisits, scope and severity of deficiencies) will impact the amount being assessed. They asked whether CMS would notify providers in advance of the actual amount that would be assessed, and whether providers would be notified about how these factors were specifically used to assess a given fee.

*Response:* We believe that the adjustment criteria outlined in this regulation can be important factors affecting the number of survey hours that would be required in a revisit survey and therefore the cost of such revisit survey. However, the final fee schedule published in this rule does not make use of all the potential factors that might otherwise be used because we believe many of the factors require more analysis. Of the criteria listed in 488.30(b), CMS is only using 488.30(b)(1)(i) and (ii) for the immediate future.

If Congressional authority for the revisit fee is renewed or extended, and CMS changes the overall methodology for calculating and collecting these fees, CMS will implement these changes through notice and comment rulemaking in the **Federal Register**. If Congressional authority for the revisit fee is renewed or extended but CMS will not be implementing any methodological changes, CMS will publish proposed and final notices in the **Federal Register** to announce and solicit comment on planned updates, adjustments, or changes to the criteria used, if changes are to be made.

For example, CMS does not plan to use criterion set forth at 488.30(b)(2)—regional differences in cost—in the immediate future. However, if CMS should decide to use it in the future, CMS will publish a notice in the **Federal Register** announcing CMS's intention to do so, describing how CMS intends to use and operationalize 488.30(b)(2), and to solicit public comment. Similarly, for technical adjustments or updates to the fee schedule (e.g. adjustments for cost of living increases), CMS will issue public notices in the **Federal Register**.

On the other hand, if CMS should decide in the future to use a completely different criterion not described in these rules, CMS will publish a notice of proposed rulemaking announcing this change in methodology.

Such future notices would address the commenters' concern regarding provider or supplier size, for example, and how the number of beds or the number of patients or residents served might affect a revisit fee.

In this final rule we do reserve the right to adjust fees based on the number of follow-up revisits conducted either decreasing or increasing fees based on the costs that are incurred by state survey agencies to conduct these multiple follow-ups. Any change to the current fee schedule in which the same revisit user fee is applied for each revisit, will be preceded by **Federal Register** notice of the planned change.

In this regulation we are providing the information needed for each provider or supplier to know the amount that they would be charged if a revisit occurs. These criteria incorporate the average cost per provider or supplier for conducting a revisit survey and the type of revisit survey conducted (onsite or offsite). We would charge the same fee each time a revisit occurs, so if a revisit revealed that the facility had not achieved full compliance and if a second revisit were required, the provider would be charged the same amount again for the second revisit.

*Comment:* One commenter suggested that the fee should be based on the total or estimated hours of service, not by the actions performed during a survey. Another commenter suggested that a "cap" be placed on the total amount of user fees associated with a single revisit and associated with a given provider. One commenter acknowledged the intent of the proposed change and encouraged CMS to adjust revisit user fees according to particularities of the states, such as staff travel time, etc.

*Response:* We proposed in the June 29, 2007 Proposed Rule to use criteria (b)(1)(i) (average cost per provider or supplier type) and (b)(1)(ii) (revisit type: Onsite or offsite), and have retained those criteria in this final rule and fee schedule. We agree with the commenter that the fee should be based on the total or estimated hours of service. We have utilized an average cost per provider or supplier based on the average costs per hour for conducting revisit surveys. We appreciate the comment regarding suggesting a "cap" on the total amount of fees associated with a single revisit. We believe the methodology in this rule conforms to the "cap" idea. As discussed in the proposed rule, providers or suppliers will be assessed one fee per revisit. As discussed in the Proposed Rule, when offsite preparation is required, as it is in many cases, the provider or supplier would not be assessed a separate revisit fee for this offsite preparation. Instead, the entire preparation and actual onsite revisit will count as an onsite revisit survey.

Based on current data analysis, CMS proposed to implement the revisit user fee utilizing only criteria identified in § 488.30(b)(1)(i) and (1)(ii). We appreciate the commenters encouragement to look at differences in State costs for the revisits. In proposed § 488.30(b)(2) we reserved the right to adjust the fees to account for regional differences in costs. It is our intent to conduct further analysis on these additional criteria in proposing future fee schedules. In this rule, the final fee schedule is based on a simpler flat-rate

methodology per provider type. If regional cost differences were invoked in any future change to the fee schedule, we would publish a proposed and final notice in advance of any such changes.

*Comment:* One commenter identified that CMS, on July 17, 2007, stated that certain provider types in California's Orange, Riverside, San Bernardino and Los Angeles Counties would be under a 2 year demonstration to re-enroll in Medicare, as well as be subject to a survey should the provider have had a Change of Ownership within the last 2 years. The commenter asked that providers not be assessed a fee if the visit is associated with this demonstration.

*Response:* We agree with the commenter and have specified that neither a provider nor a supplier will be assessed a fee if the visit is considered a "State Monitoring visit" unless the visit also meets the definition of a revisit survey in this rule. In this case, a Change of Ownership action, and other actions involved in this particular State demonstration, are considered a "State Monitoring visit" for purposes of this final regulation and final fee schedule. Therefore, providers and or suppliers participating in the two year demonstration would be exempt being assessed a revisit user fee if the revisit is associated with visits conducted solely on behalf of this demonstration and to the extent that they do not involve deficiencies in compliance with the Conditions of Participation or Coverage.

We appreciate all of the commenters' suggestions on our proposed criteria sections, and have clarifications in response to a number of the commenters' concerns. We intend to provide the requested detail in incorporating additional criteria when calculating any changes to the fee schedule for revisit user fees, if authority is provided by the Congress and through the notice and rulemaking process described earlier. We believe we have addressed concerns raised in this section, therefore we will retain the proposed language in § 483.30(b)(1) and (b)(2) as final. We accordingly have calculated the final fee schedule based on selected criteria. The final fee schedule will utilize criteria in § 488.30(b)(1)(i) and (b)(1)(ii) as proposed and finalized by this rule.

#### *Section 488.30(c)—Fee Schedule*

We proposed in § 488.30(c) that CMS will publish in the **Federal Register** the proposed and final notices of a uniform fee schedule before it adopts this schedule. The proposed and final notices would set forth the amounts of

the assessed fees based on the criteria as identified in paragraph (b) of this subpart. In future notices, any changes to the amounts of the assessed fees would include for example, adjustments based on increases to cost of living, labor and overhead costs. The proposed rule also constituted publication of the proposed fee schedule.

We based user fee calculations in the proposed rule and fee schedule on the type of revisit (onsite vs. offsite); the type of provider or supplier; the average number of hours that a revisit requires; and the average per hour cost of a revisit. We have identified the revisit survey costs below under section IV, Regulatory Impact Analysis.

We have received varying comments raised under this section. The majority of these comments referenced concerns also raised under general comments, the current survey process, and the criteria for determining the fee. We believe we have addressed these concerns in other sections. Comments received on § 488.30(c) are below:

*Comment:* One commenter believed that the **Federal Register** notice contained a number of labels displaying data regarding estimated costs and 2006 frequencies of revisit surveys, the commenter felt that based on the proposed language in Section 488.30(b) that CMS intends to exercise considerable latitude in the actual levying of fees in a specific situation. Another commenter felt that it is unfair to providers to impose fees without advance notification of the actual costs based on any adjustment criteria.

*Response:* We will publish in the **Federal Register** the proposed and final notices of a uniform fee schedule before we adopt this schedule. Both notices would set forth the amounts of the assessed fees based on the criteria as identified in section 488.30(b). It will also specify which of the criteria listed in 488.30(b)(1)–(2) will be used and how they will be operationalized.

In response to the nature of these comments, we have clarified the regulatory language and thus adopt as

final that § 488.30(c) will read: “CMS must publish in the **Federal Register** the proposed and final notices of a uniform fee schedule before it assesses revisit user fees. The notices must set forth which criteria will be used and how, as well as the amounts of the assessed fees based on the criteria, as identified in paragraph (b) of this subpart.” Language placed in bold for emphasis on the changes. We also note through the publication of this final rule that if authority for the revisit user fees is continued, we will use the current fee schedule in this rule for the assessment of such fees until such time as a new fee schedule notice is proposed and published in final form.

The final fee schedule is identified below in Table A. Summation of data and calculations regarding this final fee schedule is discussed in section V, Regulatory Impact Analysis summary below.

TABLE A.—FINAL FEE SCHEDULE FOR REVISITS SURVEYS  
[Onsite and offsite]

Facility	Fee assessed per offsite revisit survey	Fee assessed per onsite revisit survey
SNF & NF .....	\$168	\$2,072
Hospitals .....	168	2,554
HAHA .....	168	1,613
Hospice .....	168	1,736
ASC .....	168	1,669
RHC .....	168	851
ESRD .....	168	1,490

*Section 488.30(d)—Collection of Fees*

We proposed in § 488.30(d)(1) that fees for revisit surveys under this paragraph may be deducted from amounts otherwise payable to the provider or supplier. We also proposed that fees will be deposited as an offset collection to be used exclusively for survey and certification activities conducted by State survey agencies pursuant to section 1864 of the Act or by CMS, and will be available for CMS until expended. We also proposed that CMS may devise other collection methods as it deems appropriate. In determining these methods, CMS will consider efficiency, effectiveness, and convenience for the providers, suppliers, and CMS. In the Proposed Rule we stated that Methods may include: Credit card; electronic fund transfer; check; money order; and offset of collections from claims submitted.

1. § 488.30(d)(1)—Collection Methods

*Comments:* Several commenters indicated that regarding the proposed language that fees for revisits be deducted from amounts otherwise payable to the provider, they raised concern that there were no specifics as to whether these fees would be deducted all at once or on a schedule.

*Response:* In the proposed language CMS identified a number of methods for the collection of the revisit user fee. For the immediate future, we will utilize a bill pay system. Providers or suppliers who are assessed a fee will receive a notice in the mail which will include the amount of the assessed revisit fee and the revisit survey for which the fee is assessed. Included in the notice is the obligation that payment is expected to be remitted within 30 calendar days of the date of the notice. As a means of clarification and to expand on payment methods that may be beneficial to providers and suppliers and based on

the various comments, CMS will modify the last sentence of § 488.30(d)(1) by adding “any method allowed by law, including credit card; electronic fund transfer; check; money order; offset collection from claims submitted.” We will include all necessary details within this coupon notice, including to whom to direct questions, and payment remittance information. In addition, as a result of various comments regarding the time frame for when we may collect fees, and the concerns regarding the schedule of these fees, we will include an additional subparagraph § 488.30(d)(3) to this section that indicates: “Fees for revisit surveys will be due for any revisit surveys conducted during the time period for which authority to levy a revisit user fee exists.”

*Comments:* One commenter indicated that they would prefer that if fees are needed, then providers should be charged an up-front fee that does count

towards approved expenses of doing business/cost report based on bed size.

*Response:* The revisit user fees are limited to fees for revisit surveys conducted as a result of deficiencies cited during an initial certification, recertification and substantiated complaint surveys. The fee will only be applied when revisits are needed to assure substantial compliance that requirements are met. Although we appreciate the commenters statement, Congress' clear intent was that CMS assess a fee only for revisits required as a result of deficiencies cited. It would be out of the scope of our authority to assess fees for upfront survey costs.

## 2. § 488.30(d)(2)—Cost Report

*Comment:* One commenter raised concern regarding our statement: "At no time is the individual provider's cost borne by other patients." The commenter felt our statement disregards the nature of medical transactions and that these revisit user fees, if extracted from the provider's income stream, would directly impact the range and quality of the services rendered by competing on a cash basis with all other spending priorities in the practice.

*Response:* Each revisit user fee will arise from a provider's documented failure to comply with federal requirements for quality of care or safety. We hope that a provider would not respond to a fee arising from such failure by decreasing quality of care. Such an action could simply give rise to more quality compromises, more complaints, more surveys or complaint investigations, more revisits, and more fees. The result would not make economic or medical sense. We appreciate the commenter's concern that a provider might respond to a revisit fee by reducing services. This would represent a business decision on the part of the provider. An alternative would be to invest in remedial action so that quality would be improved and the prospect of future revisits and revisit fees would be reduced. We hope that providers will adopt the alternative approach.

*Comment:* Some commenters objected to the fee, but stated that if the fee were adopted then it should be considered an allowable cost on the cost report. The commenters expressed concern as to where the funds would come from if the fees were not permitted as an allowable cost on the cost report, particularly, in an industry already struggling to continue to provide services.

*Response:* We proposed in § 488.30(d)(2) that fees for revisit surveys under this section are not allowable items on a cost report, as

identified in part 413, subpart B of this chapter, under title XVIII of the Act. The revisit user fee will be levied only as a result of a provider's failing to meet basic quality of care or safety standards that are required as a condition of participation or coverage in the Medicare program. As such, it is not appropriate for a revisit user fee to be an allowable item for a cost report. To do so would lead to both cost-shifting and the counterintuitive result that more quality breakdowns could lead to more payment. For these reasons, the Secretary has put in place the necessary mechanism for which cost-shifting would be prevented. In addition, a significant number of providers and suppliers are reimbursed through the prospective payment system; as a result, only a small group of providers as compared to the overall number of providers and suppliers receive cost based reimbursements.

While the user fee program is simply intended to defray costs of the revisits, we believe that the design of the user fee program we finalize will result in a positive correlation between quality of care and amount of the fees—the better the quality of care, the lower the fees. We also expect that the prospect of fees for revisits will promote greater compliance with federal quality of care requirements, thereby making for fewer revisits and fewer fees over time.

*Comment:* A commenter stated that as a result of the financial burden of the revisit user fee, the expense for the payment of this fee would be cost-shifted to private pay residents. The commenter stated that, if the fee were to be advanced this should include a requirement that would ensure increased Medicaid/Medicare reimbursement to avoid shifting burden of added costs to private-pay residents. Another commenter felt that the fee would also amount to a shifting of funds and as a result either the money is withheld from the hospital up front as part of budget cuts or the hospital has to pay it back as part of their CMS certification process.

*Response:* We proposed in § 488.30(d)(2) that fees for revisit surveys under this section are not allowable items on a cost report, as identified in part 413, subpart B of this chapter, under title XVIII of the Act. Part 413 identifies CMS' formulating methods for making fair and equitable reimbursement for services rendered to beneficiaries of the program. Payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. This cost report also designs this reimbursement formulation

so that the individual provider's costs are not borne by other patients.

CMS believes that the assessed revisit user fee is not an allowable item for a cost report, as it should not be figured into the services provided to beneficiaries, nor should it be a cost shared amongst non-Medicare patients. CMS employs several checks and balances to deter this from occurring. CMS believes that this proposed language in § 488.30(d)(2) would prevent the inclusion of the revisit user fee costs in any future cost reports. This section will only apply to a small group of providers who receive cost-based reimbursement. A significant amount of providers and suppliers are reimbursed through the prospective payment system (PPS).

As a result of comments received to § 488.20(d)(1) and (d)(2) and CMS' further consideration, we will modify the proposed language of § 488.30(d)(1) and retain the proposed language of § 488.30(d)(2) as final. The proposed last sentence of § 488.30(d)(1) will be modified to read: "Any method allowed by law, including credit card; electronic fund transfer; check; money order; offset collection from claims submitted." The remainder of the proposed language will be retained as final.

## Section 488.30(e)—Reconsideration Process for Revisit User Fees

We proposed in § 488.30(e) that a reconsideration process shall be available to providers or suppliers that have been assessed a revisit user fee if a provider or supplier believes an error of fact, such as a clerical error, has been made. We also proposed that a request for reconsideration must be received by CMS within seven calendar days from the date identified on the revisit user fee assessment notice.

*Comment:* Several commenters believe that a reconsideration process should be available for surveyor errors and substantial errors of interpretation, and that it should not be limited to just clerical errors. Another commenter indicated that the reconsideration process should include unfounded citations. One commenter asked for clarification on what was meant by "error of fact," as a basis for requesting a reconsideration. Another commenter asked whether a provider could request a reconsideration of a fee if they were in the process of appealing deficiencies.

*Response:* The reconsideration process for revisit user fees is intended only for those situations in which a provider or supplier believes that an error of fact has been made in the application of the revisit user fee. These errors of fact would include such things

as clerical errors, billing for a fee already paid, inadvertent billing for a revisit following a validation survey of a deemed provider, or assessment of a fee when there was no revisit conducted. A request for reconsideration of an assessed revisit user fee is a separate process from any informal dispute resolution or appeal of the underlying deficiency citations.

*Comment:* Several commenters thought that limiting the window for revisit user fee reconsideration request to seven calendar days was unrealistic and requested that the timeframe for reconsideration requests be expanded to 30 calendar days. Another commenter requested that the timeframe for a reconsideration request be extended to 10 calendar days, and other commenters suggested a 14 or 15 calendar day window. However, one commenter thought that the seven day window was reasonable.

*Response:* We proposed that a request for reconsideration must be received by CMS within seven calendar days from the date identified on the revisit user fee assessment notice. CMS has considered the commenters' suggestions for extending the timeframe for submitting a reconsideration request and we have agreed to expand the timeframe for reconsideration requests to 14 calendar days from the date identified on the revisit user fee assessment notice. We will, therefore, change the timeframe for submitting a reconsideration request to 14 calendar days in the final rule. The time trigger date is the date when the assessment notice is prepared and sent. The revisit survey must have occurred prior to our assessment of a revisit user fee.

*Comment:* Several commenters suggested that, where a reconsideration determines that a revisit user fee was charged in error, any payments made should be refunded immediately, instead of applying the payment to future assessments of fees. One commenter suggested that refunds should be made within 30 days, whereas another commenter suggested 60 calendar days of approval of a reconsideration request. Commenters thought that actions related to fees should remain pending until the outcome of the reconsideration, and that a fee should not be paid until a facility exhausts its appeals; upon successful reconsideration, a provider would receive written confirmation that a fee is null and void.

*Response:* We believe that given the proposed timeframe for submitting a reconsideration request and the regulatory obligation of payment (within 30 calendar days), there would be a

limited possibility that payment would be sent without CMS providing a response to the reconsideration. We, however, believe that regulatory clarification is warranted based on the type of comments received. We have modified the proposed text to include separate subparagraphs § 488.30(e)(1)(i) and (ii), (e)(2), and (e)(3). The modified language of § 488.30(e) will read as follows:

(e) Reconsideration process for revisit user fees.

(1) CMS will review a request for reconsideration of an assessed revisit user fee—

(i) If a provider or supplier believes an error of fact has been made in the application of the revisit user fee, such as clerical errors, billing for a fee already paid, or assessment of a fee when there was no revisit conducted, and

(ii) If the request for reconsideration is received by CMS within 14 calendar days from the date identified on the revisit user fee assessment notice.

(2) CMS will issue a credit toward any future revisit surveys conducted, if the provider or supplier has remitted an assessed revisit user fee and for which a reconsideration request is found in favor of the provider or supplier. If in the event that CMS judges that a significant amount of time has elapsed before such a credit is used, CMS will refund the assessed revisit user fee amount paid to the provider or supplier.

(3) CMS will not reconsider the assessment of revisit user fees that request reconsideration of the survey findings or deficiency citations that may have given rise to the revisit, the revisit findings, the need for the revisit itself, or other similarly identified basis for the assessment of the revisit user fee.

We believe that the potential that a provider or supplier would be assessed a revisit user fee due to clerical error would be rare, when this is viewed through the overall survey process and checks and balances inherent in the survey and certification process. We believe that in the rare case that this assessment should occur, we have provided providers and suppliers with an opportunity to request a reconsideration. We, indicated, however, in § 488.30(e)(3) that “we will not reconsider the assessment of revisit user fees that request reconsideration of the survey findings or deficiency citations that may have given rise to the revisit, the revisit findings, the need for the revisit itself, or other similarly identified basis for the assessment of the revisit user fee.” We also, based on comments received, have provided providers and suppliers a greater window for submission of requests for reconsideration from 7 calendar days to 14 calendar days. We are including additional language in § 488.30(e)(2)

that identifies that we will issue a credit toward any future revisit surveys conducted if a provider or supplier has remitted an assessed revisit user fee and for which a reconsideration request is found in favor of the provider or supplier as we discussed in the preamble text of the Proposed Rule. We further clarify that we “in the event that CMS judges that a significant amount of time has elapsed before such a credit is used, CMS will refund the assessed revisit user fee amount paid to the provider or supplier.” In regards to the commenters' specific suggestion that refunds should be made within 30 calendar days, or commenters that suggested 60 calendar days, CMS will make a concerted effort to respond to requests for reconsideration within a timely manner and notify providers or suppliers that the reconsideration was determined in their favor, as applicable prior to the time frame for which they must remit payment. However, in those cases where remittance has occurred and the provider or supplier has not experienced an additional revisit survey and is then due a refund, CMS is committed to developing a system that would ensure efficient refund of any monies collected in error. CMS' present bill pay system would require more than 30 to 60 calendar day processes. We estimate that this cause for a refund may occur in less than 5% of all overall cases. At this time, CMS does not have the requisite data in which to provide specific amounts of provider or suppliers falling into this category, however we believe it will be an even lower percentage provided all the inherent checks and balances in our current survey and certification process.

*Comment:* Several commenters requested that CMS clarify the time frame for when a reconsideration decision will be made, and one commenter requested that CMS include a deadline in the regulation for responding to reconsideration requests. One commenter proposed that reconsiderations be resolved within 30 days of a reconsideration request.

*Response:* CMS is cognizant of the providers' 30 calendar day time frame for submitting payment and will ensure that reconsiderations are resolved in a timely manner. CMS will make a concerted effort to respond to request for reconsideration within a timely manner and notify provider or suppliers that the reconsideration was determined in their favor, prior to the time frame for which they must remit payment.

We appreciate comments received on time frames, refund methodology, and notification. As a result of suggestions, we have modified § 488.30(e) to include

within 14 calendar days for requests for reconsideration. Section 488.30(e) will read in final as discussed above.

#### *Section 488.30(f)—Enforcement*

We proposed in § 488.30(f) that if the full revisit user fee payment is not received within 30 calendar days or a request for reconsideration is not received within seven calendar days from the date the provider or supplier receives written notice of assessment, CMS may terminate the facility's provider agreement and enrollment in the Medicare program or the supplier's enrollment and participation in the Medicare program, and the provider or supplier may not seek Medicare payment, nor be considered a Medicare participating provider or supplier. We have changed the seven calendar day time period for filing of a reconsideration request to fourteen calendar days. Otherwise, CMS will adhere to the termination process as identified in § 489, subpart E, of this chapter.

*Comment:* Some commenters connected the discussion of revocation of billing and the termination for nonpayment as proposed in § 488.30(f) and § 489.53(a)(16). One commenter felt that termination for nonpayment within 30 days is power disproportionate to the offense and is unrelated to quality of care and safety issues. Another commenter felt that this provision is reason not to participate in Medicare, or to care for Medicare patients.

*Response:* While we proposed that a provider or supplier may also be determined not to be in compliance if a revisit user fee payment has not been received within 30 calendar days from the date identified on the assessment notice, we also state at § 424.535(a)(1) that all providers and suppliers are granted an opportunity to correct the deficient payment compliance before a final determination is made to revoke billing and enrollment privileges. We further note that a payment-due notice from CMS is preceded by a survey or complaint investigation that has found deficiencies, a correction period afforded to the provider or supplier, a revisit to confirm compliance, then a later issuance of the payment-due notice, followed by the formal 30-day advance notice to the provider. As soon as a revisit occurs, each provider or supplier will know that a revisit user fee will follow at a later date, will know the amount of the fee due from the fee schedule published in this rule, and will know that the payment will be due within 30 calendar days. While the rule specifies that enforcement action may occur if the bill has not been paid

within 30 calendar days, the total amount of planning time available to the provider or supplier will have totaled much more than the 30-calendar day period before any enforcement action may occur. Finally, the revocation of billing and enrollment privileges is not an immediate action upon the failure of a provider or supplier to remit the assessed revisit user fee. In this final rule we therefore retain the time-frames for which action will occur regarding this process and retain the amended language to § 424.535(a)(1) as final.

*Comment:* A commenter indicated that the definition of revisit survey should be revised to limit it to those revisits in which the cited deficiency includes and is subject to an enforcement action under Subpart B of Part 489.

*Response:* We have not included the commenter's suggestion to revise the term revisit survey to include "is subject to an enforcement action under subpart B of Part 489." Subpart B of part 489 governs provider agreements, not enforcement actions. However, we do agree with the premise of the commenter's suggestion and thus have modified language in § 488.30(f) to include cross references to the appropriate subpart and subsection of part 489 (governing termination) and to a subsection of part 424 (governing revocation of enrollment and billing privileges).

Section 488.30(f) will be modified to read as applicable components "pursuant to § 489.53(a)(16) of this chapter" and "pursuant to § 424.535(a)(1) of this chapter." We retain the remainder of the proposed language in § 488.30(f) as final.

### **Part 489—Provider Agreements and Supplier Approval**

#### **Subpart B—Essentials of Provider Agreements**

##### *Section 489.20 Basic Commitments*

##### *Section 489.20(u)*

We proposed to add to § 489.20 an additional paragraph that would require a provider to agree to pay revisit user fees when and if assessed.

We did not receive comments regarding this additional paragraph. However, due to technical changes, paragraph (u) is designated as paragraph (w) and we will retain the proposed language as final.

### **Subpart E—Termination of Agreement and Reinstatement After Termination**

#### *Section 489.53 Termination by CMS*

##### *Section 489.53(a)(16)*

We proposed to add a new paragraph (16) to § 489.53(a) that would create an additional basis for termination if a provider has failed to pay a revisit user fee when and if assessed.

We did not receive comments regarding this additional paragraph and thus we retain the proposed language in § 489.53(a)(16) as final.

### **III. Provisions of the Final Rule**

In this final rule we are adopting the provisions as set forth in the June 29, 2007 proposed rule with the following revisions:

All additional language proposed in § 424.535, Revocation of enrollment and billing privileges in the Medicare Program will be retained as final.

All proposed definitions in § 488.30(a) are adopted as final, except for an addition to the definition of "provider of services, provider or supplier." The final definition now includes religious nonmedical health care institutions.

All proposed language in § 488.30(b)(1) and (b)(2) criteria for determining the fee is adopted as final.

Language proposed in § 488.30(c) Fee schedule is modified by removing term "will" and inserting the term "must" where applicable, we also removed "adopts this schedule" and added "assesses revisit user fees" for clarification. In addition we include that the clarifying language "which criteria will be used and how, as well as \* \* \*," the remainder of the language is adopted as final.

The last sentence of the language proposed in § 488.30(d)(1) has been modified for clarification to state that "CMS may consider any method allowed by law, including: Credit care; electronic fund transfer; check; money order; and offset collections from claims submitted, the remainder of this paragraph is retained as final. All proposed language in § 488.30(d)(2)—the prohibition of inclusion of the revisit user fee on a provider cost report—is adopted as final. We have added a new subparagraph and new language as a result of various comments regarding the time frame for when we may collect fees, and the concerns regarding the schedule of these fees, § 488.30(d)(3) will read: "Fees for revisit surveys will be due for any revisit surveys conducted during the time period for which authority to levy a revisit user fee exists."

Language proposed in § 488.30(e) reconsideration process for revisit user fees will be modified by changing the formatting of the paragraph to include paragraphs (e)(1)(i), (e)(1)(ii), (e)(2), and (e)(3). Language in paragraph (e)(1)(i) previously proposed as first sentence in paragraph (e) is retained as final. We have modified paragraph (e)(1)(ii) by changing that a request for reconsideration must be received by CMS within 14 calendar days instead of the 7 calendar days as proposed. We have added a new paragraph (e)(2) that identifies when CMS will issue a credit or a refund of an assessed revisit user fee in the rare case of a provider or supplier remitting payment and ultimately a reconsideration is decided within their favor. We have added a new paragraph (e)(3) that identifies that a request for reconsideration of the revisit user fee may not include reconsideration of the survey findings or deficiency citations that may have given rise to the revisit, the revisit findings, or the need for the revisit itself.

All proposed language in § 488.30(f) Enforcement is adopted as final with the addition of language identifying the interconnection of changes made to both §§ 424.535(a)(1) and 489.53(a)(16). The language will read in final: "If the full revisit user fee payment is not received within 30 calendar days from the date identified on the revisit user fee assessment notice, CMS may terminate the facility's provider agreement (pursuant to § 489.53(a)(16) of this chapter) and enrollment in the Medicare program or the supplier's enrollment and participation in the Medicare program (pursuant to § 424.535(a)(1) of this chapter).

All proposed new paragraphs to § 489.20 and § 489.53 are adopted as final.

#### *Waiver of 30-Day Delay in the Effective Date*

We ordinarily provide a 30-day delay in the effective date of the provisions of a rule in accordance with the Administrative Procedure Act (APA) 5 U.S.C. 553(d). However, the delay in the effective date may be waived as, in pertinent part, "provided by the agency for good cause found and published with the rule" 5 U.S.C. 553(d)(3). The Secretary finds that good cause exists to make effective the revisit user fee and the corresponding fee schedule immediately upon display and publication in the **Federal Register**.

The good cause exception to the 30 day effective date delay provision of section 553(d) of the APA is read to be broader than the good cause exception

to the notice and comment provision of section 553(b) of the APA.

The legislative history of the APA indicates that the purpose for deferring the effectiveness of a rule under section 553(d) was to "afford persons affected a reasonable time to prepare for the effective date of a rule or rules or to take other action which the issuance may prompt." S. Rep. No. 752, 79th Cong., 1st Sess. 15 (1946); H.R. Rep. No. 1980, 79th Cong., 2d Sess. 25 (1946). In this case, affected parties do not need time to adjust their behavior before this rule takes effect. With or without a revisit fee, a provider or supplier must be found to have corrected significant deficiencies in order to avoid termination. Additionally, the application of a fee for the revisit does not place appreciable administrative burdens on the affected providers or suppliers. We do not expect appreciable cost to State survey agencies because CMS is undertaking the billing and collection of the revisit user fee.

CMS identified in the proposed rule the immediacy of this revisit user fee program and the limited nature of the Continuing Resolution. Specifically, the Continuing Resolution requires CMS to implement the revisit fee program in fiscal year 2007. Accordingly, providers and suppliers have been on notice for some time that these fees would be imposed, and do not need additional time to be prepared to comply with the requirements of this regulation. We believe that given the short time frame that CMS has to collect fees before the authority of the Continuing Resolution expires, there is good cause to waive the 30 day effective date.

#### **IV. Collection of Information Requirements**

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

#### **V. Regulatory Impact Analysis**

##### *A. Overall Impact*

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigned responsibility of

duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This final rule is not a major rule. The aggregate costs will total approximately \$37.3 million in any 1 year.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. Small businesses are small entities, either by nonprofit status or by having revenues of \$6.5 million to \$31.9 million or less in any 1 year for purposes of the RFA. In the June 29, 2007 **Federal Register**, CMS issued a proposed rule identifying its limited information to separate and identify specific providers and suppliers that may be subject to a revisit user fee by the requirements described for purposes of the RFA. CMS also identified its limited information on the total revenues collected by provider or supplier type. CMS does collect information regarding Medicare and Medicaid claims submitted, however this would not provide the requisite requirements for the RFA regarding total revenues. CMS also identified that it does collect National level information which includes personal health care expenditures and payments. Personal health care as we discussed in the proposed rule includes hospital care, professional services, nursing and home health care, all of which cover those services provided by the provider and suppliers who may be assessed a revisit user fee.

Based on the information provided within the proposed rule a few commenters felt that the user fee would add what they consider financial strains on an already strained nursing home industry, especially to stand alone, not-for-profits. Additionally, two commenters stated that the economic implication must be considered, including the potential impact on wages for employees within healthcare facilities. Another commenter requested that CMS in this section take into account State differences, citing their State's increased costs for all their home health and hospice providers, who are subject to increased fees in general and

felt this user fee would disproportionately impact these providers in their State. Another commenter felt that Home Health Agencies have been adversely impacted by stagnant and declining reimbursement from both Medicare and Medicaid in the past years.

CMS specified in the proposed rule that the providers and suppliers that may be assessed a revisit user fee fall into the category of revenues collected under personal health care funds. As such CMS calculated that the overall impact of the estimated \$37.3 million that will be assessed for revisit user fees would only amount to 2.3 percent of the \$1,560.2 million personal health care revenues collected and only 1.9 percent of all national health care expenditures of which personal health care expenditures are included.

Although we do not deny that the revisit user fee would require a payment from a provider or supplier who is assessed a fee due to the need for a revisit survey, we do not believe it will have such an economic impact that it would create additional financial strains on providers and suppliers. We believe that many providers and suppliers will pay no fees because they consistently provide high quality care, have no deficiencies identified through the survey process, and therefore will require no revisits. Thus, this rule will have minimal financial impact on those providers and suppliers. In addition, we appreciate the commenters' concern regarding their specific State's financial situation.

For the immediate future, we have calculated the user fee by provider type and by average number of hours required for a revisit survey. It is our intent that we will consider other criteria as identified in § 488.30(b), which includes regional differences when proposing and finalizing future fee schedules. Based on our information gathered, we have determined, and the Secretary certifies, that this rule will not have a significant impact on small entities based on the overall effect on revenues.

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan statistical Area (superseded by Core Based Statistical Areas) and has fewer than 100 beds. This final rule affects those small rural hospitals that have

been cited for a deficiency based on noncompliance with required conditions of participation and for which a revisit is needed to make sure that the deficiency has been corrected.

Based on the information provided as a requirement for Section 1102(b) of the Act, some commenters raised concerns that these fees will be very expensive for various rural providers or suppliers, not just rural hospitals, but also small rural Home Health Agencies and long-term care facilities in rural communities, and that CMS could be affecting the availability of care in rural areas. One commenter asked why hospitals should be exempt from the fee just because the fee may have a significant impact on them; while another commenter raised what they identified as unfairness in the frequency of surveys conducted annually for long-term care facilities versus 3 years for hospitals.

Hospitals are not exempt from the revisit user fees. While hospitals are surveyed less frequently than nursing homes, hospitals are subject to CMS complaint investigations similar to nursing home complaint investigations as well as other providers and suppliers. CMS is statutorily obligated to conduct a regulatory impact analysis for small rural hospitals as part of its rule making process. As such, we have reviewed data affecting these rural hospitals, and upon that review have determined that of all hospitals identified, 285 revisits or 3.9 percent were conducted in rural hospitals to ensure that deficiencies identified were corrected. Based on the effective time period of this proposed rule, less than 3 percent of all hospitals may in fact be assessed a revisit user fee in this current fiscal year (FY 2007), we estimate that less than 1 percent of rural hospitals will be impacted by this rule.

The statutory analysis that is required does not indicate that small rural hospitals would be exempt from regulatory requirements. Rather, it requires only that the rule making agency must determine the overall financial impact on small rural hospitals. We do not make a distinction on the quality-of-care provided to residents or patients by either urban or rural location. Federal regulations call for all residents and patients to receive adequate care. The revisit user fee will only be assessed as a result of deficiencies cited with respect to providers or suppliers not fully complying with Federal requirements.

With regard to the survey frequency, nursing homes are mandated by statute to be certified annually, whereas CMS policy calls for hospitals (both accredited and non-accredited) to be

certified or deemed certified on a 3 year cycle.

In addition, we appreciate the commenters' concern regarding the potential impact on various rural communities. For the immediate future, we have calculated the user fee by provider type and by average number of hours required for a revisit survey. It is our intent that we will consider other criteria as identified in § 488.30(b), which includes regional differences and facility size when proposing and finalizing future fee schedules. Based on our information gathered, we have determined, and the Secretary certifies, that this rule will not have a significant impact on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately \$120 million. This rule will have no mandated effect on State, local, or tribal governments and the impact on the private sector is estimated to be less than \$120 million and will only effect those Medicare providers or suppliers for which a revisit user fee is assessed based on the need to conduct a revisit survey to ensure deficient practices that were cited have been corrected.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This final rule will not substantially affect State or local governments. This final rule establishes user fees for providers and suppliers for which CMS has identified deficient practices and requires a revisit to assure that corrections have been made. Therefore we have determined that this final rule will not have a significant effect on the rights, roles, and responsibilities of State or local governments.

#### *B. Impact on Providers/Suppliers*

The source of the data used to estimate the number and cost of revisit surveys is CMS's Online Survey, Certification and Reporting (OSCAR) database. OSCAR is the repository of information about CMS and State survey agency survey actions. Data collected include the dates of surveys, survey findings, and the length of time that surveyors spent conducting the survey. State survey agencies record survey time



on the CMS-670 form. Data from the CMS-670 form are entered into OSCAR by the State survey agency. CMS analyzed average survey time length using actual data from FY 2006.

Based on information entered into OSCAR, we proposed user fees in accordance with the type of revisit survey (onsite vs. offsite); the type of provider or supplier; the average number of hours that a revisit survey requires; and the average per hour cost of a revisit survey.

**Overall Effect on Providers and Suppliers**

We estimate that there are potentially 47,804 providers and suppliers affected by the revisit user fee, although we expect only some of those providers will be charged a revisit user fee in any one particular year. We based this estimate on FY 2006 actual data. Table B below presents the key information. Of those providers and suppliers, 34.8 percent required and received a revisit survey in FY 2006, including both onsite and offsite revisits. As identified in the

proposed rule, providers and suppliers that required a revisit survey ranged widely across facility types from 87.9 percent for skilled nursing facilities (“SNFs”)/nursing facilities (“NFs”) to 2.8 percent for ambulatory surgical centers. We did not include transplant centers in FY 2006 and 2007 calculations due to lack of available cost and revisit data at this time. Transplant centers will be newly surveyed providers starting in FY 2008, and will be subject to revisit fees at the hospital rate.

**TABLE B.—PERCENTAGE OF PROVIDERS/SUPPLIERS THAT HAD A REVISIT SURVEY FY 2006**

	Total providers/suppliers <sup>1</sup>	Total revisit survey for FY 2006 (onsite & offsite)	Number of providers/suppliers that required revisit survey(onsite & offsite)	Percent of provider/suppliers that required revisit survey (onsite & offsite)
SNF/NF <sup>2</sup> .....	15,172	29,426	13,350	87.9
Hospitals <sup>3</sup> .....	7,139	853	594	8.3
HHAs .....	8,901	1,585	1,320	14.8
Hospices .....	3,077	307	246	7.9
ASC .....	4,735	188	133	2.8
RHC .....	3,828	216	204	5.3
ESRD .....	4,952	929	781	15.7
<b>Total</b> .....	<b>47,804</b>	<b>33,504</b>	<b>16,662</b>	<b>34.8</b>

<sup>1</sup> Online Survey, Certification and Reporting (OSCAR) database (via PDQ, Provider Summary Table), includes providers considered active at any time in the fiscal year.

<sup>2</sup> Total number does not include Medicaid-only Nursing Facilities.

<sup>3</sup> Total includes accredited and non-accredited hospitals, as well as psychiatric hospitals, and critical access hospitals.

*Comments:* One commenter observed that, in CMS’ impact analysis and fee proposals, CMS chose to include critical access hospitals in a single grouping with all other hospitals, even though section 1861(e) of the Social Security Act states that the term hospital does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1)). The commenter stated that because critical access hospitals are typically smaller and less complex organizations than most other hospitals, the context clearly does not require their inclusion with hospitals in this analysis and that it would seem that the average length of an onsite revisit survey, and the corresponding assessed fee, would be less than that of other hospitals. CMS should at least present the relevant data on critical access hospitals.

*Response:* We included critical access hospitals in our hospital average fee due to their similar functions and surveying process. We believe this issue raised by commenters has merit which will require further analysis and we will consider looking at critical access hospitals in future fee schedules as its own distinct entities. We agree that revisit time may be affected by many

factors in addition to size of the facility. We have adopted a relatively straightforward method of calculating the user fee. If the Congress renews or extends the authority to collect the revisit user fee for any considerable time period, we intend to build into the fee schedule a means to take into account facility size and location to the extent that we find such factors make a significant difference in the time and actual cost of the revisits.

**Frequency and Duration of Revisit Surveys**

There are many differences across providers and suppliers in the frequency and duration of revisit surveys. Skilled nursing facilities/nursing facilities accounted for 83 percent of total onsite revisit surveys conducted in FY 2006 following the identification of deficiencies from standard surveys. Home health agencies accounted for 6 percent of onsite revisit surveys in FY 2006, while ESRDs and hospitals accounted for 8 percent, 4 percent each. Hospice facilities, ambulatory surgical centers, and rural health clinics combined comprised the remaining 3 percent of revisits. The average length of an onsite revisit

survey varied from 7.6 hours for rural health clinics to 22.8 hours for hospitals. In comparison, offsite revisit surveys conducted averaged one and a half hours (1.5) across all providers and suppliers.

**Fee Schedule for Onsite Revisit Surveys**

We will base the final fee schedule on the average length of time required for revisit surveys by provider or supplier type in FY 2006. Averages were calculated separately by type of provider or supplier, and the hours for revisit surveys were separated by either standard health surveys, complaint surveys, or offsite surveys. A cost of \$100 per hour was incurred in FY 2005, which was the basis of the cost estimates in the Continuing Resolution. We project that the actual current cost based on inflation factors and processing expenses is \$112 per hour and we will use this projected cost in setting the fee schedule. In order to obtain this inflation factor, CMS utilized FY 2005 annual expenditures derived from CMS-435 form that captures a State’s cumulative expenditures and divided this by information obtained from CMS-670 form that identifies State’s workload hours or survey hours,

as discussed above. The product of this calculation resulted in dollars per hour or cost incurred for conducting surveys. CMS then took this number and multiplied this by a composite rate of inflation that was obtained from percentage change calculations identified in annual and semi-annual indexes prepared by the U.S. Department of Labor's Consumer Price Index for Wage Earners and Clerical Workers (CPI-W). See U.S. Department

of Labor, Bureau of Labor Statistics. *Summary of Annual and Semi-Annual Indexes*. ONLINE. 2007. Bureau of Labor Statistics. Available: [http://www.bls.gov/ro3/fax\\_9125.htm](http://www.bls.gov/ro3/fax_9125.htm) [22 Feb 2007]. In our fee schedule, the \$112 average cost per hour is then multiplied by the average hours for the revisit surveys to achieve the average fee cost per onsite revisit survey as identified in Table C below. For the present, we will not adjust fees based on the length of

individual revisit surveys, but will assess a flat fee per revisit survey, based on provider or supplier type. We expect these costs to increase annually to incorporate economic changes, cost of living increases, labor and overhead costs expenses if authority for the revisit fee is continued in the future.

All revisit user fees will be assessed after publication of this final rule.

TABLE C.—REVISIT USER FEE ASSESSMENT BASED ON AVERAGE LENGTH OF ONSITE REVISIT SURVEYS\*

Facility	Average length of onsite revisit survey (hrs)	Fee assessed per revisit survey (hrs × \$112)
SNF/NF .....	18.5	\$2,072
Hospitals** .....	22.8	2,554
HHA .....	14.4	1,613
Hospice .....	15.5	1,736
ASC .....	14.9	1,669
RHC .....	7.6	851
ESRD .....	13.3	1,490

\* This includes onsite revisit surveys according to both Standard Health Surveys and Complaint Surveys.  
 \*\* Transplant center revisits will be charged at the hospital rate.

Proposed Fee Schedule for Offsite Revisit Surveys

For offsite revisit surveys, we expect a revisit user fee of \$168 assessed regardless of provider or supplier type. Based again on recorded survey time on the CMS-670 form, it was assessed that offsite revisit surveys on average take one and a half hours (1.5) across all providers and suppliers. We calculated the base hourly fee of \$112 multiplied by an average of one and a half hours to arrive at the \$168 fee assessed per offsite revisit survey.

All revisit user fees will be assessed after publication of this final rule and fee schedule.

Costs for All Revisit User Fees Assessed

We expect the combined costs for all providers and suppliers for all revisit

surveys in FY 2007 to total approximately \$37.3 million, with onsite revisit surveys amounting to approximately \$34.6 million and offsite revisit surveys totaling approximately \$2.7 million. However, actual fees assessed in FY 2007 will be much less than this annual amount, since we will not charge for revisits that occur prior to publication of this final regulation. The rule will take effect the date of publication. In order to give maximum consideration to the fiscal impact of the rule that would occur if it were in force for an entire year, we provide here both annual and quarterly estimates of the impact as listed below in Tables D and E. If authority for the revisit user fees is continued beyond FY 2007, we will use the current fee schedule in this rule for the assessment of fees until a new fee

schedule notice is proposed and published as final.

In Table D below, we provide the projected quarterly costs based on the fee schedule of this final rule. We expect the combined costs for all providers and suppliers for all onsite revisit surveys for one quarter to total approximately \$8.6 million. We first utilized the total number of onsite revisit surveys for FY 2006, took the expected revisit user fees assessed per revisits as calculated in Table B above estimated by provider or supplier and multiplied this number by the number of onsite revisit surveys expected for one quarter. We then totaled all providers and suppliers to achieve the total quarterly costs for all onsite revisit surveys.

TABLE D.—ESTIMATED QUARTERLY COSTS FOR ONSITE REVISIT SURVEYS

Facility	Number of onsite revisit surveys (FY 2006)	Fee assessed per onsite revisit survey (hrs × \$112) (See Table B)	Number of onsite revisit surveys est. for quarter*	Total costs for onsite revisit surveys for quarter
SNF & NF .....	14,288	\$2,072	3,572	\$7,401,184
Hospitals .....	575	2,554	144	367,776
HHA .....	1,068	1,613	267	430,671
Hospice .....	256	1,736	64	111,104
ASC .....	95	1,669	24	40,056
RHC .....	149	851	37	31,487
ESRD .....	698	1,490	175	260,750
Total .....	17,129	.....	4,283	8,643,028

\*Total number of onsite revisit surveys divided by 4 and rounded up based on FY 2006 actual data.

We expect the combined costs for all providers and suppliers for all offsite revisit surveys to total \$687,960 on a quarterly basis. In Table E below, we first estimated by provider or supplier

the number of offsite revisit surveys expected for one quarter and multiplied this number by the expected revisit user fee of \$168 per offsite revisit survey as discussed above. We then totaled all

providers and suppliers to achieve the total costs for all offsite revisit surveys for one quarter.

TABLE E.—ESTIMATED QUARTERLY COSTS FOR OFFSITE REVISIT SURVEYS

Facility	Number of offsite revisit surveys (FY 2006)	Fee assessed per offsite revisit survey (\$112 × 1.5 hrs)	Number of offsite revisit surveys est. for quarter*	Total costs for offsite revisit surveys for quarter
SNF & NF .....	15,138	\$168	3,785	\$635,880
Hospitals .....	278	168	70	11,760
HHA .....	517	168	129	21,672
Hospice .....	51	168	13	2,184
ASC .....	93	168	23	3,864
RHC .....	67	168	17	2,856
ESRD .....	231	168	58	9,744
Total .....	16,375	.....	4,095	687,960

\*Total number of offsite revisit surveys divided by 4 and rounded up based on FY 2006 actual data.

As shown in Table F below, we provide the total costs expected had the rule been in effect for an entire FY 2007,

as well as the costs we would expect to offset in the final quarter of the fiscal year if the rule were in effect for the

entire last quarter of FY 2007 or an entire quarter in the future.

TABLE F.—TOTAL COSTS COMBINED FOR ALL REVISIT SURVEYS PER FISCAL YEAR & QUARTER

	FY 2007	One quarter*
Onsite Revisit Surveys .....	\$34,565,760	\$8,643,028
Offsite Revisit Surveys .....	2,751,000	687,960
Total Costs All Revisits .....	37,316,760	9,330,988

\*One quarter's costs are based on quarterly revisit surveys rounded up to the nearest whole number as shown in Tables D & E; multiplying Table F last quarter numbers in column 2 by 4 would create a slightly larger cost than identified in FY 2007 column 1 above.

As discussed above, we have excluded Medicaid-only facilities (such as Intermediate Care Facilities for the mentally Retarded (ICFs/MR)), comprehensive outpatient rehabilitation facilities, providers of outpatient physical therapy or speech pathology services, independent laboratories, portable x-ray centers, physical therapists in independent practice, federally qualified health centers, chiropractors, Religious nonmedical health care institutions (RNHCIs) in all proposed rate-setting calculations.

We also expect that the revisit user fee will have some effect in motivating providers and suppliers to improve quality, or if quality problems do occur, to ensure that quality lapses are corrected more quickly than in the past. Both of these positive effects would result in fewer revisit surveys being necessary. However, CMS does acknowledge that the revisit user fee may have a counter effect of prompting long-term care facilities to engage in the informal dispute resolution process to dispute State survey agency decisions

more frequently in order to avoid the assessment of a fee.

We received a wide variety of comments on the discussion of the impact of this rule on providers and suppliers and we have summarized these comments below.

1. Unfairness in Charging Same Fees

*Comments:* A commenter stated that it is unfair to charge the same revisit fee, regardless of the seriousness or number of deficiencies.

*Response:* We appreciate the commenters' implicit suggestion that the amount of the revisit fee should be scaled to reflect differences in the number and seriousness of the deficiencies identified. This rule provides the basis to take such factors into greater account in the future. If the Congress renews or extends the user fee authority beyond FY 2007, we plan to examine this idea in more depth and act on it if it is determined to be feasible and correlated well with actual revisit cost. In the fee schedule in this final rule we take some small steps in the direction of acknowledging that more

deficiencies or deficiencies of greater severity may take more revisit time. Under the current design in this rule, many providers will pay no fees because they consistently provide high quality care, have no deficiencies identified through the survey process, and therefore will require no revisits. Other providers may require some revisits but with minimal costs because the deficiencies are not serious, and the revisit may be accomplished through an offsite revisit survey. We have established a much lower fee for offsite revisit surveys since actual costs to the survey program for offsite revisit surveys are much less than the costs for onsite revisit surveys, and the user fee is intended only to recoup average actual costs. We believe we have designed the user fee program to result in a positive correlation between quality of care and amount of the fees—the better the quality of care, the lower the fees. We also expect that the prospect of fees for revisits will promote greater compliance with federal quality of care requirements, thereby making for fewer revisits and fewer fees over time.

2. Equalized Rate State

*Comments:* A few commenters noted that North Dakota is an equalized rate state, meaning that nursing homes cannot charge a per diem rate for private pay residents that exceed the per diem rate that Medicaid pays. Revenues are limited and funds could be better spent to improve the quality of care.

*Response:* In North Dakota nursing homes are the only Medicaid providers mandated to have equalization of rates. Equalization of rates means nursing facilities are prohibited from charging private paying residents more than the rate set by Medicaid. Medicaid controls and sets the rate for all nursing home residents except the 5 percent controlled by Medicare. The legislature sets the rate equal to the equalization rate. This final rule will only apply to Medicare providers and suppliers and to dually-participating nursing facilities.

3. Charges Should Not Be Based on Averages

*Comment:* A commenter felt that, rather than charging on an average fee basis by provider type, the charges should be based on the specific number of hours required to do the onsite visit and be based on the actual hourly salary

cost of the surveyor, plus limited overhead. This would help ensure that the fees will not exceed actual cost and will be specific to the level of effort involved in the visit.

*Response:* We disagree. CMS does use a national average actual cost per hour (surveyors salaries, associated overheads and miscellaneous costs for travel, office space and equipment rentals, etc.) in calculating the average hours and costs for each provider type; Skilled Nursing Homes, HHA, Hospice, etc. revisits. However, we use average costs per provider type and do not individualize the fee to the exact number of revisit hours for any one provider, since we judge such extremely specific pricing to be so administratively expensive at this point in time that it would detract significantly from the fiscal benefits of the revisit user fee.

*Comment:* A few commenters argued that fees should reflect the actual cost of conducting each providers survey, rather than being based on national average costs for each type of provider.

*Response:* We recognize that there are differences among States and among particular facilities that lead to different costs of conducting revisit surveys. At

this time, CMS has determined to charge an average fee per provider type, but will consider changing the fee schedule in the future to account for differences among particular providers.

4. Fees Are Excessive

*Comment:* A few commenters felt that the size of the fee was excessive.

*Response:* The size of the revisit fee is sufficient to cover the costs that state survey agencies incur in conducting the surveys. We do not believe that the amount of the revisit user fee will be very significant except for those providers that have a persistent problem sustaining compliance with federal requirements and may have many revisits as a result. CMS's expectation is that all providers remain in compliance with federal regulations at all times. These federal regulations establish minimally acceptable standards. The user fee will cover the costs that the state agency incurs in ensuring that violations of federal regulations have been corrected. The correction of many minor deficiencies can be evaluated by an offsite revisit survey, which will result in a nominal charge.

C. Final Fee Schedule

Facility	Fee assessed per offsite revisit survey	Fee assessed per onsite revisit survey
SNF & NF .....	\$168	\$2,072
Hospitals .....	168	2,554
HHA .....	168	1,613
Hospice .....	168	1,736
ASC .....	168	1,669
RHC .....	168	851
ESRD .....	168	1,490

D. Alternatives Considered

The revisit user fee in the Continuing Resolution addresses important resource issues in the Medicare survey and certification programming budget. To implement this revisit user fee process, CMS is required to promulgate a proposed regulation and proposed fee schedule. CMS has attempted through a variety of methods to encourage ways of providers and suppliers to improve quality and thus decrease the need to conduct revisit surveys for deficiencies cited prior to the inclusion of a revisit user fee included in the FY 2007 Continuing Resolution. CMS continues to conduct outreach and educational efforts, quality analysis studies, and review of current regulatory requirements to focus in on health and safety measures. In its outreach efforts, CMS staff continues to present at trade association meetings representing home

health agencies, hospices, skilled nursing facilities/nursing facilities, and other large accreditation organizations. CMS staff speaks to new developments within survey and certification policy, updating of regulations, and expectations that CMS has for those providing services to its Medicare beneficiaries. CMS in its continued outreach and educational efforts surrounding health and safety requirements regularly posts and shares any modification of policies or program on its CMS survey and certification Web site and through its survey and certification online course delivery systems. See U.S. Centers for Medicare & Medicaid Services. "Certification & Compliance." ONLINE. 2007. CMS. Available: [http://www.cms.hhs.gov/SurveyCertificationEnforcement/01\\_Overview.asp](http://www.cms.hhs.gov/SurveyCertificationEnforcement/01_Overview.asp). CMS also devoted a substantial part of the work of the

Quality Improvement Organizations (QIOs) to educate providers and suppliers on best practices and expectations for meeting Federal health and safety requirements. Despite these efforts, there continue to be many providers and suppliers that fail to meet Medicare conditions of participation, conditions for coverage or requirements and require revisit surveys to ensure compliance with Federal quality of care requirements. In addition, costs for these revisits continue to increase. CMS believes that the assessment of revisit user fees, as directed in the Continuing Resolution, is a piece of the larger efforts to address health care providers and suppliers that have failed to comply with Federal quality of care requirements.

In accordance with Executive Order 12866, this rule has been reviewed by the Office of Management and Budget.

**List of Subjects****42 CFR Part 424**

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 488**

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

**42 CFR Part 489**

Health facilities, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR Chapter IV, parts 424, 488, and 489 as set forth below:

**PART 424—CONDITIONS FOR MEDICARE PAYMENT**

■ 1. The authority citation for part 424 continues to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302 and 1395hh).

**Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges**

■ 2. Section 424.535 is amended by revising paragraph (a)(1) introductory text to read as follows:

**§ 424.535 Revocation of enrollment and billing privileges in the Medicare program.**

(a) \* \* \*

(1) *Noncompliance.* The provider or supplier is determined not to be in compliance with the enrollment requirements described in this section, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter. The provider or supplier may also be determined not to be in compliance if it has failed to pay any user fees as assessed under part 488 of this chapter. All providers and suppliers are granted an opportunity to correct the deficient compliance requirement before a final determination to revoke billing privileges.

\* \* \* \* \*

**PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES**

■ 1. The authority citation for part 488 is revised to read as follows:

**Authority:** Secs. 1102 and 1871 of the Social Security Act, unless otherwise noted

(42 U.S.C. 1302 and 1395(hh)); Pub.L. 110–5, H.J. Res. 20, § 20615(b)(2007).

**Subpart A—General Provisions**

■ 2. Part 488, subpart A is amended by adding a new § 488.30 to read as follows:

**§ 488.30 Revisit user fee for revisit surveys.**

(a) *Definitions.* As used in this section, the following definitions apply:

*Certification* (both initial and recertification) means those activities as defined in § 488.1.

*Complaint surveys* means those surveys conducted on the basis of a substantial allegation of noncompliance, as defined in § 488.1.

*Provider of services, provider, or supplier* has the meaning defined in § 488.1, and ambulatory surgical centers, transplant centers, and religious nonmedical health care institutions subject to § 416.2, § 482.70, and § 403.702 [C8] of this chapter, respectively, will be subject to user fees unless otherwise exempted.

*Revisit survey* means a survey performed with respect to a provider or supplier cited for deficiencies during an initial certification, recertification, or substantiated complaint survey and that is designed to evaluate the extent to which previously-cited deficiencies have been corrected and the provider or supplier is in substantial compliance with applicable conditions of participation, requirements, or conditions for coverage. Revisit surveys include both offsite and onsite review.

*Substantiated complaint survey* means a complaint survey that results in the proof or finding of noncompliance at the time of the survey, a finding that noncompliance was proven to exist, but was corrected prior to the survey, and includes any deficiency that is cited during a complaint survey, whether or not the cited deficiency was the original subject of the complaint.

(b) *Criteria for determining the fee.*

(1) The provider or supplier will be assessed a revisit user fee based upon one or more of the following:

(i) The average cost per provider or supplier type.

(ii) The type of revisit survey conducted (onsite or offsite).

(iii) The size of the provider or supplier.

(iv) The number of follow-up revisits resulting from uncorrected deficiencies.

(v) The seriousness and number of deficiencies.

(2) CMS may adjust the fees to account for any regional differences in cost.

(c) *Fee schedule.* CMS must publish in the **Federal Register** the proposed and final notices of a uniform fee schedule before it assesses revised revisit user fees. The notices must set forth which criteria will be used and how, as well as the amounts of the assessed fees based on the criteria as identified in paragraph (b) of this subpart.

(d) *Collection of fees.*

(1) Fees for revisit surveys under this section may be deducted from amounts otherwise payable to the provider or supplier. As they are collected, fees will be deposited as an offset collection to be used exclusively for survey and certification activities conducted by State survey agencies pursuant to section 1864 of the Act or by CMS, and will be available for CMS until expended. CMS may devise other collection methods as it deems appropriate. In determining these methods, CMS will consider efficiency, effectiveness, and convenience for the providers, suppliers, and CMS. CMS may consider any method allowed by law, including: Credit card; electronic fund transfer; check; money order; and offset collections from claims submitted.

(2) Fees for revisit surveys under this section are not allowable items on a cost report, as identified in part 413, subpart B of this chapter, under title XVIII of the Act.

(3) Fees for revisit surveys will be due for any revisit surveys conducted during the time period for which authority to levy a revisit user fee exists.

(e) *Reconsideration process for revisit user fees.*

(1) CMS will review a request for reconsideration of an assessed revisit user fee—

(i) If a provider or supplier believes an error of fact has been made in the application of the revisit user fee, such as clerical errors, billing for a fee already paid, or assessment of a fee when there was no revisit conducted, and

(ii) If the request for reconsideration is received by CMS within 14 calendar days from the date identified on the revisit user fee assessment notice.

(2) CMS will issue a credit toward any future revisit surveys conducted, if the provider or supplier has remitted an assessed revisit user fee and for which a reconsideration request is found in favor of the provider or supplier. If in the event that CMS judges that a significant amount of time has elapsed before such a credit is used, CMS will refund the assessed revisit user fee amount paid to the provider or supplier.

(3) CMS will not reconsider the assessment of revisit user fees that

request reconsideration of the survey findings or deficiency citations that may have given rise to the revisit, the revisit findings, the need for the revisit itself, or other similarly identified basis for the assessment of the revisit user fee.

(f) *Enforcement.* If the full revisit user fee payment is not received within 30 calendar days from the date identified on the revisit user fee assessment notice, CMS may terminate the facility's provider agreement (pursuant to § 489.53(a)(16) of this chapter) and enrollment in the Medicare program or the supplier's enrollment and participation in the Medicare program (pursuant to § 424.535(a)(1) of this chapter).

**PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL**

■ 3. The authority citation for part 489 continues to read as follows:

**Authority:** Secs. 1102, 1819, 1861, 1864(m), 1866, 1869, and 1871 of the Social Security Act, 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh).

**Subpart B—Essentials of Provider Agreements**

■ 4. Section 489.20 is amended by adding a new paragraph (w) to read as follows:

**§ 489.20 Basic commitments.**

\* \* \* \* \*

(w) To comply with § 488.30 of this chapter, to pay revisit user fees when and if assessed.

■ 5. Section 489.53 is amended by adding a new paragraph (a)(16) to read as follows:

**§ 489.53 Termination by CMS.**

(a) \* \* \*

(16) It has failed to pay a revisit user fee when and if assessed.

\* \* \* \* \*

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program) (Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: September 7, 2007.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: September 12, 2007.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. E7-18458 Filed 9-18-07; 8:45 am]

**BILLING CODE 4120-01-P**