§ 54.4980G–4 [Corrected]

3. On page 30504, column 3, § 54.4980G–4(f) *Example 4.,* line 9 from the top of the column, the language ''February, 2008. Employer T satisfies the'' is corrected to read ''February, 2010. Employer T satisfies the''.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E7–12587 Filed 6–28–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 424, 488, and 489

[CMS–2268–P]

RIN 0938–AO96

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would allow CMS to charge revisit user fees to health care facilities cited for deficiencies during initial certification, recertification, or substantiated complaint surveys. 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'' would affect only those providers or suppliers for which CMS has identified deficient practices and requires a revisit to assure that corrections have been made. The fees are estimated at $37.3 million annually and would recover the costs associated with the Medicare Survey and Certification program's revisit surveys. The fees would take effect on the date of publication of the final rule, and would be available to CMS until expended.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on August 27, 2007.

ADDRESSES: In commenting, please refer to file code CMS–2268–P. Because of staff and resource limitations, we cannot accept comments by facsimile (Fax) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Submit electronic comments on CMS regulations with an open comment period.'' (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2268–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–2268–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members. Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Carla McGregor, (410) 786–0663, (Policy). Kathryn Linstromberg, (410) 786–8279 (Policy). Edward F. Mortimore, (410) 786–3509 (Data). David Escobedo, (410) 786–5401 (Budget).

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–2268–P and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.cms.hhs.gov/eRulemaking.* Click on the link ''Electronic Comments on CMS Regulations'' on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

SUPPLEMENTARY INFORMATION:

I. Background

A. Survey & Certification Compliance Process

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.

Medicare is a Federal insurance program that provides a wide range of benefits for specific periods of time to Medicare beneficiaries through providers and suppliers participating in the program. The Social Security Act (''Act'') designates those providers and suppliers that are subject to Federal health care quality standards. The Federal Government makes payment for services through designated fiscal intermediaries, carriers, and Medicare administrative contractors to the providers and suppliers.

- Providers, in Medicare terminology, include patient care institutions such as hospitals, critical access hospitals, hospices, nursing homes, and home health agencies.
- Suppliers, in Medicare terminology, include entities for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics, and qualified health centers.

Medicaid is a State program that provides medical services to clients of the State public assistance program and, at the State's option, other needy individuals. When services are furnished through institutions that must be certified for Medicare, the institutional standards must be met for Medicaid as well. State survey agencies, under agreements between the State and the Secretary, carry out the Medicare certification process. Section 1864(a) of the Act directs the Secretary to use the State health agencies or ''other appropriate agencies,'' also known in this context as State survey agencies, to determine whether health care institutions meet Federal standards.

B. Authority To Assess Revisit User Fees

The President's HHS budget for FY 2007 included $35 million in new user fees to finance the costs associated with CMS' Medicare survey and certification program's activities. The President's HHS budget for FY 2007 included projections based on FY 2005 numbers. CMS has updated that information based on FY 2006 actual data and thus all other references to the amount projected reference $37.3 million instead of $35 million. We have included these calculations in section IV Regulatory Impact Analysis below. The Continuing Appropriations Resolution (''Continuing Resolution'') budget bill passed by the Congress and signed by the President directed HHS to implement the fees for FY 2007, 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. Not withstanding 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)).

Revisit surveys are conducted pursuant to the citing of deficiencies that were found during initial certification, recertification, or substantiated complaint surveys and are conducted for the purpose of verifying the fact that the deficiencies previously cited have been corrected.

A crucial component to survey activities are the agreements established under section 1864 of the Act between the Secretary and the State survey agencies to determine that an institution meets the statutory definition for the provider type and that it satisfies all conditions of participation or regulatory requirements, as well as, any additional requirements as determined by the Secretary. Section 1864(e) of the Act, in relevant part regarding the imposition of fees involving survey activities, states:

> Notwithstanding any other provision of law, the Secretary may not impose, or require a State to impose, any fee on any facility or entity subject to a determination under subsection (a), or any renal dialysis facility subject to the requirements of section 1881(b)(1), for any such determination or any survey relating to determining the compliance of such facility or entity with any requirement of this title (other than any fee relating to section 353 of the Public Health Service Act).

The Congress enacted section 20615(b) of the Continuing Resolution with the knowledge of section 1864(e) of the Act and took specific action to carve out fees for revisits as a result of cited deficiencies while being careful not to specify fees for initial surveys conducted for those newly entering the Medicare/Medicaid Program or for conducting statutorily based recertification surveys. The Secretary believes it was the Congress' intent to harmonize the Continuing Resolution with section 1864(e) of the Act by limiting the fees to those quality assurance functions, that is, revisits, necessary to confirm the correction of previously-identified deficiencies. This belief is consistent with the rule of statutory interpretation that provides that, ''[w]here there are two acts upon the same subject, effect should be given to both, if possible. *See Posadas* v. *National City Bank of New York,* 296 U.S. 497, 503 (1936).

Although the Secretary believes that the Continuing Resolution language should be read to coexist with the language of the Act, to the extent that section 20615(b) of the Continuing Resolution and section 1864(e) of the Act are perceived to be irreconcilable, the Secretary must give effect to the more recent Continuing Resolution for the period of availability of the appropriations. It is well established that it is in Congress' power to abrogate or modify a treaty or earlier legislation that it created. *See Fund for Animals, Inc.* v. *Kempthorne,* 472 F.3d 872, 876 (D.C. Cir. 2006) (citing *Fund for Animals* v. *Norton,* 374 F.Supp.2d 91, 103 (D.D.C. 2005)) (''Congress clearly has the power to abrogate or modify a treaty or earlier legislation, and when it does so, that is the final word''). In resolving similar conflicts, the Federal courts have applied the principle of *lex posterior derogate legi priori* also known as ''lex posterior'' or the ''last-in-time'' rule; that is to say, where two statutory provisions appear to conflict, the later in time prevails. *See Fund for Animals,* 472 F.3d at 878 (''[T]he Supreme Court has long recognized that a later enacted statute trumps an earlier-enacted treaty to the extent the two conflict.''). The rule is premised on the idea that the interpretation and application of statutes should reflect the most recent expression of the Congress' intent. Therefore, application of the last-in-time rule would result in section 20615(b) of the Continuing Resolution superseding section 1864(e) of the Act to the extent that the two provisions conflict.

The Secretary believes the intended section 20615(b) of the Continuing Resolution to apply only during this current fiscal year (FY 2007) and that a decision on making a permanent change to the statute will be deferred until a later time. *See* B–303268 Op. GAO–Legal (2005), *http://www.gao.gov/decisions/appro/303268.htm* (concluding that a nonpermanent provision in an appropriations resolution, which conflicts with a prior enacted appropriations act, is effective under the ''last-in-time'' rule, but will expire at the end of the fiscal year). Since the Congress did not expressly state otherwise, and the authority under section 1864(e) of the Act is permanent, the authority under section 20615(b) of the Continuing Resolution extends only through FY 2007.

Accordingly, section 20615(b) of the Continuing Resolution would only constitute a variation to the general prohibition of fees under section 1864(e) of the Act through September 30, 2007. These considerations lend further credence to the Secretary's belief that it was the Congress' intent to harmonize the two provisions.

Based on the Congress' knowledge of section 1864(e) of the Act, the unambiguous nature of section 20615(b) of the Continuing Resolution, and the principles of *lex posterior,* the Secretary has the authority to propose and implement this revisit user fee rule.

II. Provisions of the Proposed Regulations

Part 424—Subpart P—Requirements for Establishing and Maintaining Medicare Billing Privileges

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

[If you wish to comment on issues in this section, please include the caption ''424.535(a)(1)—REVOCATION OF ENROLLMENT AND BILLING PRIVILEGES IN THE MEDICARE PROGRAM—USER FEE ADDITION'' at the beginning of your comments.]

We propose 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 propose 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 beginning of the paragraph will continue to read the same and the ending of 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. The addition of this sentence does not provide an opportunity for additional comments on any other component of part 424 or § 424.535.

Part 488—Survey, Certification, and Enforcement: Subpart A—General Provisions.

Section 488.30 Revisit User Fee for Revisit Surveys

We propose a new § 488.30 which sets forth proposed regulations that would identify the circumstances under which providers or suppliers would 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

[If you choose to comment on issues in this next section, please include the caption ''Section 488.30(a) ''DEFINITIONS'' at the beginning of your comments]

We propose in § 488.30(a) to define terms associated with this paragraph. Those terms include: ''certification,'' ''complaint surveys,'' ''substantiated complaint survey,'' ''provider of services,'' ''provider,'' ''supplier,'' and ''revisit survey.''

''Certification (Initial or Recertification)''

We propose 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.'' Conditions of participation apply to providers of Medicare services, other than skilled nursing facilities, while conditions for coverage apply to suppliers of Medicare services.

We propose that a user fee under this proposed rule will be assessed for revisit surveys conducted to evaluate the extent to which deficiencies identified during initial certification or recertification surveys have been corrected.

''Complaint Surveys''

We propose 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)

CMS through its authority under the certification and survey process provisions of sections 1819(g), 1864, and 1891(c) of the Act has identified in the State Operations Manual (SOM) the procedures by which complaints/incidents will be handled by CMS and the State survey agencies. CMS identifies a complaint as ''an allegation of noncompliance with Federal and/or State requirements.'' An allegation is further identified as ''an assertion of improper care or treatment that could result in the citation of a Federal deficiency.'' *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'').

''Substantiated Complaints Surveys''

The Continuing Resolution includes the term ''substantiated complaints surveys.'' We propose 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. The Secretary believes its term ''substantial allegation of noncompliance'' identified in § 488.1 is the direct correlation for this term in the HHS budget. Thus, this proposed regulation would consider ''substantiated complaints surveys'' to be surveys conducted based on CMS or the State survey agency receiving a ''substantial allegation of noncompliance'' where the non-compliance has been confirmed through a complaint survey.

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

''Provider of Services, Provider, or Supplier''

The terms ''provider of services,'' ''provider,'' or ''supplier'' are already defined in § 488.1. We propose 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 propose that a ''provider of services'' or ''provider'' subject to user fees, 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 will also be subject to user fees and have been newly defined in § 482.70 of this chapter. *See* Medicare Program; Hospital Conditions of Participation: Requirements for

Approval and Re-approval of Transplant Centers to Perform Organ Transplants, published March 30, 2007 (72 FR 15198) (codified at 42 CFR part 482). We propose that, for FY 2007, ''providers of services'' or ''providers'' that will not be assessed a revisit user fee as defined in this proposed rule to be comprehensive outpatient rehabilitation facilities and providers of outpatient physical therapy or speech pathology services. We have excluded these providers because the time and cost involved in conducting revisits to these providers are minimal or the nature in which oversight is conducted is not the same as for those providers included. Medicaid-only ''providers of services'' or ''providers'' will not be assessed a user fee.

We also propose a ''supplier'' subject to user fees, as it applies in this 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 subject to user fees under this proposed rule are independent laboratories, portable x-ray centers, physical therapists in independent practice, Federally Qualified Health Centers (FQHCs), and chiropractors. We have excluded these suppliers because the time and cost involved in conducting revisits to these suppliers are minimal or the nature in which oversight is conducted is not the same as for those suppliers included. Medicaid-only ''suppliers'' will not be assessed a user fee.

This 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.

''Revisit Survey''

We propose to define 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 propose that for purpose of this rule, revisit surveys include both offsite and onsite. The fees associated with offsite (''desk'') surveys will be less than the fees assessed for onsite surveys. Most revisit surveys include both onsite and offsite time, but a number of revisit surveys may be accomplished through desk review only. Oftentimes an onsite revisit survey will require offsite preparation; in these cases only one user fee will be assessed for an onsite revisit survey.

Section 488.26 provides direction as to how compliance with the conditions of participation, conditions for coverage, or other regulatory requirements is determined. Specifically, section 488.26 provides 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. While the conditions of participation, conditions for coverage, and requirements for determining compliance are unique to each provider and supplier, the Secretary has created common terms for purposes of survey and certification.

Revisit policies have been established based on provider/supplier type.

Skilled Nursing Facilities/Dually-participating Nursing Facilities. The current policy for skilled nursing facilities and dually-participating nursing facilities permits two onsite revisits, 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. Second revisits may be required if the deficiencies are not fully corrected, if there continue to be negative outcomes from the originally-cited noncompliance, or if new and serious deficiencies are present during the revisit. Further, if the State determines that a third revisit is necessary, due to continuing noncompliance, it must be approved at the discretion of the CMS Regional Office. CMS does not permit a third revisit except in unusual circumstances. *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* (''SOM–SNF/NF Enforcement Process'').

Hospitals/Home Health Agencies/Hospices/Ambulatory Surgical Centers/Rural Health Clinics/End-Stage Renal Disease Centers. 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 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. A revisit is conducted if a State survey agency and/or CMS receives from the provider or supplier a credible allegation that it is in compliance, following a determination that the provider or supplier had failed to substantially meet Federal requirements. If a provider or supplier fails to make a credible allegation of compliance, a revisit is not necessary, since the provider agreement is then subject to termination.

Revisits Related to Immediate Jeopardy. Revisits are also conducted, if possible, before a termination results in response to an immediate jeopardy situation. An immediate jeopardy situation is one in which the provider or supplier's noncompliance with one or more requirements of participation has caused, or is likely to cause, severe temporary or permanent injury, disability or death to an individual. A provider or supplier in this situation will be terminated from the Medicare/Medicaid program within 23 calendar days from the day the deficiency was cited if no corrective action steps are taken and completed. A revisit is conducted if there is a credible allegation from the provider or supplier that it has corrected the threat or the deficiency cited as immediate jeopardy. If CMS and the State survey agency disagree as to whether an immediate jeopardy exists, it may be necessary for CMS and the State survey agency to conduct a revisit together. *See* U.S. Centers for Medicare & Medicaid Services. *State Operations Manual*, ''Additional Program Activities.'' Online. 2007. CMS. Available: *http://www.cms.hhs.gov/manuals/downloads/som107c03.pdf.*

We welcome public comment regarding all definitions proposed in § 488.30(a).

Section 488.30(b)—Criteria for Determining the Fee

[If you choose to comment on issues in this next section, please include the caption ''Section 488.30(b) CRITERIA FOR DETERMINING THE FEE'' at the beginning of your comments]

We propose in § 488.30(b) to provide the criteria for determining the user fee. We propose that for initial implementation of revisit user fees in FY 2007, 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—onsite review or offsite review.

We welcome public comment regarding the criteria we propose to use in FY 2007 to establish the revisit user fee: That of average cost per revisit survey and the provider or supplier type and the type of the revisit survey.

We also propose that exceptions to the assessment of a user fee will be identified based on the type of visit conducted. For example, we propose 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. A ''State monitoring visit'' refers to visits by the State survey agency to oversee a provider/supplier's compliance status during bankruptcy, after a change of ownership, during or shortly after the removal of immediate jeopardy when the purpose of the visit is to ensure the welfare of the residents/clients/patients by providing an oversight presence, and in other circumstances as authorized by the CMS regional office where the provider/supplier is located. See SOM–Complaint, § 5077; *see also* SOM–SNF/NF Enforcement Process, § 7504.

Likewise, we also propose that neither a provider nor a supplier will be assessed a fee if the visit is associated with Medicare provider or supplier compliance with Life Safety Code (LSC) requirements. The LSC is a set of fire protection requirements, that covers construction, protection, and operational features designed to provide a reasonable degree of safety from fire, smoke, and panic. The LSC, which is revised periodically, is a publication of the National Fire Protection Association. The basic requirement for facilities participating in the Medicare and Medicaid programs is compliance with the 2000 edition of the LSC. The State survey agency determines whether the LSC survey is to occur before, after, or simultaneously with the health survey. Most States require an initial LSC survey before admitting patients prior to becoming operational. *See* U.S. Centers for Medicare & Medicaid Services. ''Life Safety Code Requirements.'' Online. 2007. CMS. Available: *http://www.cms.hhs.gov/CertificationandComplianc/11_LSC.asp#TopOfPage.* In addition, we also propose that neither a provider nor a supplier will be assessed a fee if the visit is associated with a Federal Monitoring Survey, such as a Federal look-behind survey.

We also propose in § 488.30(b)(1)(iii) through (b)(1)(iv) 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. These factors impact cost in that the 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 propose in § 488.30(b)(2) that CMS may adjust the fees to account for any regional differences in cost.

We welcome public comment regarding the criteria for determining the revisit user fee.

Section 488.30(c)—Fee Schedule

[If you choose to comment on issues in this next section, please include the caption ''Section 488.30(c) ''FEE SCHEDULE'' at the beginning of your comments]

We propose 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. This proposed rule also constitutes publication of the proposed fee schedule for this fiscal year.

For FY 2007, we based user fee calculations 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 proposed the user fee costs below under section IV, Regulatory Impact Analysis.

Section 488.30(d)—Collection of Fees

[If you choose to comment on issues in this next section, please include the caption ''Section 488.30(d) COLLECTION OF FEES'' at the beginning of your comments]

We propose 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 propose 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 propose 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. Methods may include: Credit card; electronic fund transfer; check; money order; and offset of collections from claims submitted.

We welcome public comment on the forms of payment CMS proposes it will accept from providers and suppliers for the assessed revisit user fee.

We propose 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 at no time is the individual provider's costs 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).

We welcome public comment regarding the prohibition of the assessed revisit user fee being an item on a provider or supplier cost report.

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

[If you choose to comment on issues in this next section, please include the caption ''Section 488.30(e) RECONSIDERATION PROCESS FOR REVISIT USER FEES'' at the beginning of your comments]

We propose 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 propose 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.

Once CMS has determined that a revisit user fee should be put into effect, CMS shall notify the provider or supplier of its intention to charge a revisit user fee and the reasons for charging the fee, and shall give the provider or supplier an opportunity to request a reconsideration due to an error of fact. If a provider or supplier believes that a revisit user fee should be reconsidered, due to an error of fact, it should submit to CMS a written statement, and any supporting evidence, to that effect within seven calendar days, either through its authorized officials or through its legal representative.

If, upon reconsideration, it was found that a revisit fee was assessed due to error of fact, and the provider or supplier has made a payment of the assessed revisit user fee, then CMS shall credit the initial revisit payment against any future assessments of revisit fees. CMS believes this situation will be rare. CMS believes given the proposed time frame for which providers/suppliers have to submit this reconsideration request (seven calendar days) and based on the proposed regulatory obligation of payment (within 30 calendar days, as discussed below), there would be a limited possibility that payment would be sent without CMS providing a response to the reconsideration. In the case that this does occur and CMS credits the initial revisit payment against any future revisit fees, CMS will provide a refund following its reconciliation period.

We welcome public comment on the proposed section on the reconsideration of revisit user fees, including discussion regarding crediting against future assessments and the provision of refunds.

Section 488.30(f)—Enforcement

[If you choose to comment on issues in this next section, please include the caption ''Section 488.30(f) ''ENFORCEMENT'' at the beginning of your comments]

We propose 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. CMS will adhere to the termination process as identified in § 489, subpart E, of this chapter.

We welcome public comment on the proposed 30 calendar provision for receipt of full payment, and the seven calendar provision for the receipt of request for reconsideration.

Part 489—Provider Agreements and Supplier Approval

Subpart B—Essentials of Provider Agreements

Section 489.20 Basic Commitments

Section 489.20(u)

[If you choose to comment on issues in this next section, please include the caption ''Section 489.20(u)—BASIC COMMITMENTS'' at the beginning of your comments]

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

Subpart E—Termination of Agreement and Reinstatement After Termination

Section 489.53 Termination by CMS

Section 489.53(a)(16)

[If you choose to comment on issues in this next section, please include the caption ''Section 489.53(a)(16)—TERMINATION BY CMS'' at the beginning of your comments]

We propose 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.

III. 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.

IV. Regulatory Impact Analysis

[If you choose to comment on issues in this next section, please include the caption ''REGULATORY IMPACT ANALYSIS'' at the beginning of your comments]

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 reassigns 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 proposed rule would not be considered a major rule. The aggregate costs would total approximately $37.3 million in any one 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 one year for purposes of the RFA. CMS currently has 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. The percentage by type of providers and suppliers that may be assessed a revisit user fee is identified in Table A below, which discusses the overall percentage of providers and suppliers impacted. CMS also has 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. Based on available information in *2006 CMS Statistics,* at the time of publication, CMS does collect National level information which includes personal health care expenditures and payments. Personal health care 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. Personal health care expenditures amounted to $1,560.2 billion dollars in calendar year 2004 for which we have the latest information. *See* U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. ''2006 CMS

Statistics.'' Online. 2006. CMS, Office of Research, Development, and Information. Available: *http://www.cms.hhs.gov/CapMarketUpdates/downloads/2006CMSStat.pdf.* (Published July 2006). Table 36, pg. 31 [''2006 CMS Statistics'']. The providers and suppliers that may be assessed a revisit user fee would fall into the category of revenues collected under personal health care funds. CMS notes it must compare different year data sources, calendar year 2004 for personal health care funds, and FY 2006 actual data to project costs for FY 2007, we roughly estimate that the $37.3 million that would be assessed for revisit user fees would only amount to 2.3% of the $1,560.2 million personal health care revenues collected and only 1.9% of all national health care expenditures of which personal health care expenditures are included. *See* ''2006 CMS Statistics,'' Table 36, Pg. 31. We have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on small entities based on the overall effect on revenues. This is a proposed rule and we are soliciting public comments regarding any available information that may affect the percentage of revenues estimated with the implementation of this rule.

In addition, 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 603 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 proposed 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 FY 2006 actual data from CMS's Online Survey, Certification and Reporting (OSCAR) database of the 7,139 hospitals identified 2,776 or 3.8% were classified as rural hospitals. Of all hospitals identified 285 revisits or 3.9% 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% 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% of rural hospitals will be impacted by this proposed rule. Currently CMS has limited data at this time to identify how many of those revisits that will be conducted may be onsite versus offsite which will determine the amount of the revisit user fee that may be assessed. We have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on small rural hospitals. This is a proposed rule and we are soliciting public comments regarding any available information that may affect rural hospitals as identified.

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 would 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 would 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 rule would not substantially affect State or local governments. This proposed 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 proposed rule will not have a significant affect 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 propose 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 47,804 providers and suppliers. We based this estimate on FY 2006 actual data. Of those providers and suppliers, as identified in Table A below, based on FY 2006 actual data 34.8% required a revisit survey, this included both onsite and offsite revisits. Of this 34.8%, skilled nursing facilities (''SNFs'')/nursing facilities (''NFs'') made up 87.9% whereas ambulatory surgical centers made up a low of 2.8% of providers/suppliers that required a revisit survey. 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.

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

	Total providers/suppliers [1]	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 [2]	15,172	29,426	13,350	87.9
Hospitals [3]	7,139	853	594	8.3
HHAs	8,901	1,585	1,320	14.8
Hospices	3,077	307	246	7.9

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

	Total providers/ suppliers [1]	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)
ASC	4,735	188	133	2.8
RHC	3,828	216	204	5.3
ESRD	4,952	929	781	15.7
Total	47,804	33,504	16,662	34.8

[1] Providing Data Quickly (PDQ) system, Provider Summary Table, includes providers considered active at any time in the fiscal year.
[2] Total number does not include Medicaid-only Nursing Facilities.
[3] Total includes accredited and non-accredited hospitals, as well as psychiatric hospitals, and critical access hospitals.

Frequency and Duration of Revisit Surveys

There are numerous 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 a standard 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.

Proposed Fee Schedule for Onsite Revisit Surveys

We propose to base the 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 costs estimates in the Continuing Resolution. We project that the actual cost in FY 2007 based on inflation factors and processing expenses is $112 per hour and we would 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* [22 Feb 2007]. In our proposed 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 B below. For Fiscal Year 2007, 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.

All revisit user fees will be assessed in the last quarter of FY 2007. Revisit user fees will be assessed if a revisit survey is determined necessary.

TABLE B.—REVISIT USER FEE ASSESSED BASED ON AVERAGE LENGTH OF ONSITE REVISIT SURVEYS *

Facility	Average length of onsite revisit survey (hrs)	Fee assessed per revisit survey (hrs x $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.

Proposed Fee Schedule for Offsite Revisit Surveys

For offsite revisit surveys, we expect a revisit user fee of $168 assessed despite 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 in the last quarter of FY 2007. Revisit user fees will be assessed if a revisit survey is determined necessary.

Costs for all Revisit User Fees Assessed

We expect the combined costs for all providers and suppliers for all revisit surveys for FY 2007 to be a little under $37.3 million. Onsite revisit surveys will total a little under $34.6 million and offsite revisit surveys will total approximately $2.7 million. The rule would take effect the date of publication of the final rule. We provide below an explanation for quarterly costs listed in Tables C and D.

In Table C below, we provide the projected quarterly costs for the final quarter of FY 2007. 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 C.—ESTIMATED QUARTERLY COSTS FOR ONSITE REVISIT SURVEYS

Facility	Number of onsite revisit surveys (FY 2006)	Fee assessed per onsite revisit surveys (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. In Table D 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 D.—ESTIMATED QUARTERLY COSTS FOR OFFSITE REVISIT SURVEYS

Facility	Number of offsite revisit surveys (FY 2006)	Fee assessed per offsite revisit surveys ($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	8	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 E below, we provide the total costs expected for FY 2007, as well as the costs we expect to offset in the final quarter of this fiscal year by assessing Revisit User Fees for revisit surveys conducted.

TABLE E.—TOTAL COSTS COMBINED FOR ALL REVISITS SURVEYS PER FISCAL YEAR & QUARTER

	FY 2007	Last quarter FY 2007*
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

*Last quarter FY 2007 costs are based on quarterly revisit surveys rounded up to the nearest whole number as shown in Table C & D, multiplying Table E 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, 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, and chiropractors in all proposed rate-setting calculations.

We also expect that the revisit user fee would 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 providers or suppliers 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 welcome public comment including data on any additional time and costs burden that may affect the public by the assessment of a revisit user fee.

C. 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 address 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 continue to present at trade association meetings representing home health agencies, hospices, Skilled nursing facilities/nursing facilities, and other large accreditation organizations. CMS staff speak 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.* 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.

We welcome public comment that would provide some additional insight on other methods that would help to decrease the need for conducting revisits. We welcome input that would address those providers or suppliers who continue to fail to meet Federal quality of care requirements and how we can work collaboratively to ensure quality of care for Medicare beneficiaries. We also seek data or other supported sources that may identify and help to solve the concerns regarding quality and other policy avenues.

In accordance with Executive Order 12866, this proposed 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 Recording 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 proposes to amend 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 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 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* as defined in § 488.1, and ambulatory surgical centers and transplant centers subject to § 416.2 and § 482.70 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 will publish in the **Federal Register** the proposed and final notices of a uniform fee schedule before it adopts this schedule. The notices will set forth 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. Methods may include: 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.

(e) *Reconsideration process for revisit user fees.* CMS will review revisit user fees if a provider or supplier believes an error of fact has been made, such as clerical errors. A request for reconsideration must be received by CMS within seven calendar days from the date identified on the revisit user fee assessment notice.

(f) *Enforcement.* If the full revisit user fee payment is not received within 30 calendar days from the date the provider or supplier receives 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.

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 (u) to read as follows:

§ 489.20 Basic commitments.

* * * * *

(u) 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: April 9, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 6, 2007.

Michael O. Leavitt,

Secretary.

[FR Doc. 07–3196 Filed 6–26–07; 4:00 pm]

BILLING CODE 4120–01–P