DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 488

[CMS–2278–IFC3]

RIN 0938–AP22

Revisit User Fee Program for Medicare Survey and Certification Activities

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

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements the continuation of the revisit user fee program for Medicare Survey and Certification activities, in accordance with the statutory authority in the Continuing Appropriations Resolution entitled, “Making further continuing appropriations for the fiscal year 2008, and for all other purposes,” Public Law 110–137 (“Continuing Resolution”) passed by the Congress and signed by the President on December 14, 2007. On September 19, 2007, we published a final rule that established 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 previously-identified deficiencies have been corrected.

DATES: Effective date: These regulations are effective January 18, 2008, and applicable beginning December 14, 2007. Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on March 18, 2008.

ADDRESSES: In commenting, please refer to file code CMS–2278–IFC3. 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–2278–IFC3, P.O. Box 8010, 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–2278–IFC3, 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) 786–7185 in advance of 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: Kelley Tinsley, (410) 786–6664.

SUPPLEMENTARY INFORMATION: Submitting Comments: As the public was provided an opportunity to comment on the substance of the rule during the comment period prior to the publication of the September 19, 2007 final rule, and as the substance of the rule is not changed by this interim final rule with comment period, we are accepting comments only to the extent that they pertain to the applicability of the new authority for the rule. You can assist us by referencing the file code CMS–2278–IFC3.

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 be available for public inspection as they are received, generally beginning approximately three 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

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. In the September 19, 2007 Federal Register (72 FR 53628) we published the Revisit User Fee Program final rule. That final rule set forth final requirements and a 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 substantiated complaint survey.

The Centers for Medicare & Medicaid Services (CMS) has designated CMS to the Department of Health and Human Services (HHS) has designated CMS to meet 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 of the Medicare program. The revisit user fee will be assessed for revisits conducted in order to determine whether deficiencies cited as a result of failing to satisfy federal quality of care requirements have been corrected.

Pursuant to the requirements of the Continuing Appropriations Resolution budget bill for fiscal year (FY) 2007, the Secretary directed CMS to implement the revisit user fees for FY 2007 for certain providers and suppliers for which a revisit was required to confirm that previously-identified failures to meet federal quality of care requirements had been remedied. The fees recover the costs associated with the Medicare Survey and Certification program’s revisit surveys. The primary purpose for implementing the revisit user fees is to ensure the continuance of CMS Survey and Certification quality assurance activities that improve patient care and safety. The fees became effective upon publication September 19, 2007, when the final rule was published.

II. Provisions of the Interim Final Rule

The current Continuing Resolution, Public Law 110–137, amends Public Law 110–16 Division B by striking the date specified in section 106(3) and inserting “December 21, 2007”. The current Continuing Resolution authorizes HHS to continue to impose revisit user fees until December 21, 2007, as follows:

* * * Sec. 101. Such amounts as may be necessary, at a rate for operations as provided in the applicable appropriations Acts for fiscal year 2007 and under the authority and conditions provided in such Acts, for continuing the imposition of fees (including the costs of direct loans and loan guarantees) that are not otherwise specifically provided for in this joint resolution, that were conducted in fiscal year 2007, and for which appropriations, funds, or other authority were made available in the following appropriations Acts:

* * * * * * *

(3) December 21, 2007. As directed by the Secretary, in the September 19, 2007 Federal Register (72 FR 53628), we established the revisit user fee program for revisit surveys. We put forth in regulation the relevant definitions, criteria for determining the fees, the schedule, procedures for the collection of fees, the reconsideration process, enforcement and regulatory language addressing enrollment and billing privileges, and provider agreements. In the September 19, 2007 final rule, cost projections were based on FY 2006 actual data and were expected to amount to $37.3 million for FY 2007. These calculations were included in section IV of the final rule (72 FR 53642).

We stated in the final rule that, “if authority for the revisit user fee is continued, we will use the current fee schedule in [the final rule] for the assessment of such fees until such time as a new fee schedule notice is proposed and published in final form.” (72 FR 53628). The current Continuing Resolution continues the authority of the FY 2007 Continuing Resolution from December 14, 2007 through December 21, 2007. Accordingly, the revisit fees will continue to be assessed for the entire time period authorized by the current Continuing Resolution.

III. Response to Comments

Because of the large number of public comments we normally receive on Federal Register documents, we are not always able to acknowledge or respond to all of them individually. We will consider all comments we receive by the date and time specified in the DATES section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking and Delay in Effective Date

We ordinarily publish a notice of proposed rulemaking in the Federal Register and invite public comment on the proposed rule in accordance with 5 U.S.C. 553(b) of the Administrative Procedure Act (APA). The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. We find that the notice-and-comment procedure is unnecessary in this circumstance because providers and suppliers have already been provided notice and an opportunity to comment on the substance of this rule. This interim final rule with comment merely updates the Congressional authority under which the rule operates. Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

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 waive the 30-day effective date delay.
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. This rule merely updates the authority under which the revisit fee is assessed and does not provide any additional requirements for the affected parties. Moreover, 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 we are undertaking the billing and collection of the revisit user fee.

We identified in the September 19, 2007 final rule the immediacy of this revisit user fee program and the specific statutory requirement contained limited in the Continuing Resolution that required us to implement the revisit user fee program in FY 2007. Accordingly, providers and suppliers have been on notice for some time that these fees will be imposed, and do not need additional time to be prepared to comply with the requirements of this rule. We believe that given the short timeframe that we have to collect fees before the statutory authority of the current Continuing Resolution expires, there is good cause to waive the 30-day effective date.

V. 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.

VI. 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 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 one year). This rule is not a major rule. The aggregate costs will 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 $120 million or less in any one year for purposes of the RFA. The September 19, 2007 final rule provided an analysis on the impact of small entities (72 FR 53642–3). The analysis published in the final rule remains valid. Since this interim final rule with comment merely updates the Congressional authority under which the rule operates, we have determined 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 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 ensure that the deficiency has been corrected. We identified in the September 19, 2007 final rule that for the effective period of that rule that less than 3 percent of all hospitals may be assessed a revisit user fee and that less than 1 percent of those hospitals would be rural hospitals (72 FR 53643). The analysis published in the final rule remains valid. Since this interim final rule with comment merely updates the Congressional authority under which the rule operates, we maintain 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 one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $120 million. This interim final rule with comment 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 supplier 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 interim final rule with comment will not substantially affect State or local governments. This 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 interim final rule with comment will not have a significant effect on the rights, roles, and responsibilities of State or local governments.

B. Impact on Providers/Suppliers

There is no change on the impact on providers and suppliers with the publication of this interim final rule with comment. The impact remains as discussed in the final rule (72 FR 53643).

Final Fee Schedule for Onsite and Offsite Revisit Surveys

The FY 2007 fee schedule published on September 19, 2007 (72 FR 53647) in the final rule will be retained. As noted in the final rule, the published fee schedule will be used by CMS for the assessment of fees until a new fee schedule is proposed and published in final form. The calculations used to
determine the fee as identified in the final rule will be the same (72 FR 53645–6). We will continue to assess a flat fee based on provider or supplier type and type of revisit survey conducted. Table A below identifies the final fee schedule.

**TABLE A.—FINAL FEE SCHEDULE**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Fee assessed per offsite revisit survey</th>
<th>Fee assessed per onsite revisit survey</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNF &amp; NF</td>
<td>$168</td>
<td>$2,072</td>
</tr>
<tr>
<td>Hospitals</td>
<td>168</td>
<td>2,554</td>
</tr>
<tr>
<td>HHA</td>
<td>168</td>
<td>1,613</td>
</tr>
<tr>
<td>Hospice</td>
<td>168</td>
<td>1,736</td>
</tr>
<tr>
<td>ASC</td>
<td>168</td>
<td>1,669</td>
</tr>
<tr>
<td>RHC</td>
<td>168</td>
<td>851</td>
</tr>
<tr>
<td>ESRD</td>
<td>168</td>
<td>1,490</td>
</tr>
</tbody>
</table>

We anticipated that the combined costs for all providers and suppliers for all revisit surveys in FY 2007 would total approximately $37.3 million on an annual basis, with onsite revisit surveys amounting to approximately $34.6 million and offsite revisit surveys totaling approximately $2.7 million. (72 FR 53645). However, actual fees assessed in FY 2007 were much less than this amount, since CMS did not charge for revisits that occurred prior to publication of the final regulation. Since we continue to operate under this same estimate for FY 07, we provide below monthly estimates of the impact for the period of the current Continuing Resolution in Tables B and C. For the period of the current Continuing Resolution, we will use the FY 2007 fee schedule established in the final rule for the assessment of fees until a new fee schedule notice is proposed and published as final.

**TABLE C.—OFFSITE REVISIT SURVEYS—ESTIMATED WEEKLY COSTS**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Number of offsite revisit surveys (FY 2006)</th>
<th>Fee assessed per offsite revisit survey ($112 x 1.5 hrs)</th>
<th>Number of offsite revisit surveys est. for 1 week*</th>
<th>Weekly costs for offsite revisit surveys **</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNF &amp; NF</td>
<td>15,138</td>
<td>$168</td>
<td>291</td>
<td>$48,907</td>
</tr>
<tr>
<td>Hospitals</td>
<td>278</td>
<td>168</td>
<td>5</td>
<td>898</td>
</tr>
<tr>
<td>HHA</td>
<td>517</td>
<td>168</td>
<td>10</td>
<td>1,670</td>
</tr>
<tr>
<td>Hospice</td>
<td>51</td>
<td>168</td>
<td>1</td>
<td>168</td>
</tr>
<tr>
<td>ASC</td>
<td>93</td>
<td>168</td>
<td>2</td>
<td>300</td>
</tr>
<tr>
<td>RHC</td>
<td>67</td>
<td>168</td>
<td>1</td>
<td>216</td>
</tr>
<tr>
<td>ESRD</td>
<td>231</td>
<td>168</td>
<td>4</td>
<td>746</td>
</tr>
</tbody>
</table>

We expect the combined costs for all providers and suppliers for all offsite revisit surveys to total $52,905 for the period of the current Continuing Resolution. In Table C below, we first estimated by provider or supplier the number of offsite revisit surveys expected for an entire fiscal year, and multiplied this number by the expected revisit user fee of $168 per offsite revisit survey to obtain the annual cost of surveys. We then divided this number by 52 to obtain the weekly cost of offsite revisit surveys to obtain the total costs for offsite revisit surveys for the period of the current Continuing Resolution (roughly 1 week).

**TABLE B.—ONSITE REVISIT SURVEYS—ESTIMATED WEEKLY COSTS**

<table>
<thead>
<tr>
<th>Facility</th>
<th>Number of onsite revisit surveys (FY 2006)</th>
<th>Fee assessed per onsite revisit survey (hrs x $112)</th>
<th>Number of onsite revisit surveys est. for 1 week*</th>
<th>Monthly costs for onsite revisit surveys **</th>
</tr>
</thead>
<tbody>
<tr>
<td>SNF &amp; NF</td>
<td>14,288</td>
<td>$2,072</td>
<td>275</td>
<td>$569,321</td>
</tr>
<tr>
<td>Hospitals</td>
<td>575</td>
<td>2,554</td>
<td>11</td>
<td>28,241</td>
</tr>
<tr>
<td>HHA</td>
<td>1,068</td>
<td>1,613</td>
<td>21</td>
<td>33,128</td>
</tr>
<tr>
<td>Hospice</td>
<td>256</td>
<td>1,736</td>
<td>5</td>
<td>8,546</td>
</tr>
<tr>
<td>ASC</td>
<td>95</td>
<td>1,669</td>
<td>2</td>
<td>3,049</td>
</tr>
<tr>
<td>RHC</td>
<td>149</td>
<td>851</td>
<td>3</td>
<td>2,438</td>
</tr>
<tr>
<td>ESRD</td>
<td>698</td>
<td>1,490</td>
<td>13</td>
<td>20,000</td>
</tr>
</tbody>
</table>

Total: 17,129 ………………………………………………………………………………….. 330 664,723

*Estimated total numbers of onsite revisit surveys per week were rounded up after dividing yearly survey totals from FY 2006 actual data by 52.

**Weekly costs may differ from the multiple of weekly revisits and fee per revisit due to rounding.

In Table B below, we provide the projected costs for the period of this current Continuing Resolution based on the fee schedule of the final rule. We expect the combined costs for all providers and suppliers for all onsite revisit surveys for the period of this current Continuing Resolution to total approximately $665,000. We first multiplied the total number of onsite revisit surveys in one year by the expected revisit user fees assessed per revisits as finalized in Table A above, estimated by provider or supplier, to obtain the annual cost of revisit surveys. We then divided this number by 52 to obtain the weekly cost per provider or supplier of onsite revisit surveys to obtain the total costs for onsite revisit surveys for the period of the current Continuing Resolution (roughly 1 week). We then totaled all providers and suppliers to achieve the total costs for all onsite revisit surveys for the period of this current Continuing Resolution.
As shown in Table D below, we provide the aggregate costs expected as projected for the entire FY 2007, as well as the costs we would expect to offset for the period of the current Continuing Resolution.

<p>| TABLE D. — TOTAL COSTS COMBINED FOR ALL REVISITS SURVEYS PER FISCAL YEAR &amp; PERIOD OF CR |</p>
<table>
<thead>
<tr>
<th>Onsite Revisit Surveys</th>
<th>Offsite Revisit Surveys</th>
<th>Total Costs All Revisits</th>
</tr>
</thead>
<tbody>
<tr>
<td>$34,565,760</td>
<td>$2,751,000</td>
<td>37,316,760</td>
</tr>
</tbody>
</table>

* CR period’s costs are based on CR period revisit surveys rounded up to the nearest whole number as shown in Table B & C.

E. Alternatives Considered

We considered a number of alternatives to the revisit user fee program. Such alternatives were discussed in the final rule published on September 19, 2007 (72 FR 53647). We affirm the continuing validity of that analysis. The current Continuing Resolution provides CMS with the authority to continue projects or activities as was otherwise provided for in FY 2007, and as such CMS is required to publish an interim final rule with comment. This interim final rule with comment merely updates the Congressional authority under which the rule operates.

In accordance with Executive Order 12866, this rule was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 488

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

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV, part 488 as set forth below:

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)); Continuing Resolution Pub. L. 110–137 H.J. Res. 69.

(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: January 4, 2008.

Kerry Weems,
Acting Administrator, Centers for Medicare & Medicaid Services

Approved: January 15, 2008.

Michael O. Leavitt,
Secretary.

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 25

Foreign Acquisition

CFR Correction

In Title 48 of the Code of Federal Regulations, Chapter 1 (Parts 1 to 51), revised as of October 1, 2007, on page 508, in section 25.1101, in paragraph (b)(2)(iii), remove “$58,550” and add “$64,786” in its place.

[FR Doc. 08–55501 Filed 1–17–08; 8:45 am]

BILLING CODE 1505–01–D