Supporting Statement for Provider-Based Status Regulations
Contained in 42 CFR 413.24 and 413.65
CMS-R-240

A. Background

When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), enacted on August 5, 1997, added section 1833(t) to the Social Security Act (the Act) authorizing implementation of a PPS for hospital outpatient services. In addition, the hospital outpatient prospective payment system also applies to partial hospitalization services furnished by community mental health centers. The Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), enacted on November 29, 1999, made major changes that affected the hospital outpatient PPS (OPPS). The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554), enacted on December 21, 2000, made further changes in the OPPS. Although the statutory effective date for the outpatient prospective payment system was January 1, 1999, implementation of the new system was delayed because of year 2000 systems concerns.

On September 8, 1998, CMS published a proposed rule (63 FR 47552) to establish in regulations a PPS for hospital outpatient services, to eliminate the formula-driven overpayment for certain hospital outpatient services, and to extend reductions in payment for costs of hospital outpatient services. On June 30, 1999, CMS published a correction notice (64 FR 35258) to correct a number of technical and typographic errors in the September 1998 proposed rule including the proposed amounts and factors used to determine the payment rates.

On April 7, 2000, CMS published a final rule with comment period (65 FR 18434) that addressed the provisions of the PPS for hospital outpatient services scheduled to be effective for services furnished on or after July 1, 2000. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. These outpatient services are classified according to a list of ambulatory payment classifications (APCs). The April 7, 2000 final rule with comment period also established requirements for provider departments and provider-based entities and prohibited Medicare payment for non-physician services furnished to a hospital outpatient by a provider or supplier other than a hospital unless the services are furnished under arrangement. In addition, this rule extended reductions in payment for costs of hospital outpatient services as required by the BBA and amended by the BBRA. Medicare regulations governing the hospital OPPS are set forth at 42 CFR part 419.

On June 30, 2000, CMS published a notice (65 FR 40535) announcing a delay in implementation of the OPPS from July 1, 2000 to August 1, 2000. CMS implemented the OPPS on August 1, 2000.

On August 3, 2000, CMS published an interim final rule with comment period (65 FR 47670) that modified criteria that CMS uses to determine which medical devices are eligible for transitional pass-through payments. The August 3, 2000 rule also corrected and clarified certain provider-based provisions included in the April 7, 2000 rule.

On November 13, 2000, CMS published an interim final rule with comment period (65 FR 67798). This rule provided for the annual update to the amounts and factors for OPPS payment rates effective for services furnished on or after January 1, 2001. CMS implemented the 2001 OPPS on January 1, 2001. CMS also responded to public comments on those portions of the April 7, 2000 final rule that implemented related provisions of the BBRA and public comments on the August 3, 2000 rule.

On August 24, 2001, CMS published a proposed rule (66 FR 44672) that would revise the OPPS to implement applicable statutory requirements, including relevant provisions of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2002 (BIPA) and changes arising from our continuing experience with this system. It also described proposed changes to the amounts and factors used to determine the payment rates for Medicare hospital outpatient services paid under the PPS. The changes applied to services furnished on or after January 1, 2002.

On November 2, 2001, CMS published a final rule (66 FR 55857) that announced the Medicare OPPS conversion factor for calendar year 2002. In addition, it described the Secretary's estimate of the total amount of the transitional pass-through payments for CY 2002 and the implementation of a uniform reduction in each of the pass-through payments for that year.

On November 2, 2001, CMS also published an interim final rule with comment period (66 FR 55850) that set forth the criteria the Secretary will use to establish new categories of medical devices eligible for transitional pass-through payments under Medicare's OPPS.

On November 30, 2001, CMS published a final rule (66 FR 59856) that revised the Medicare OPPS to implement applicable statutory requirements, including relevant provisions of BIPA, and changes resulting from continuing experience with this system. It addition, it described the CY 2002 payment rates for Medicare hospital outpatient services paid under the PPS. This final rule also announced a uniform reduction of 68.9 percent to be applied to each of the transitional pass-through payments for certain categories of medical devices and drugs and biologicals.

On December 31, 2001, CMS published a final rule (66 FR 67494) that delayed, until no later than April 1, 2002, the effective date of CY 2002 payment rates and the uniform

reduction of transitional pass-through payments that were announced in the November 30, 2001 final rule. In addition, this final rule indefinitely delayed certain related regulatory provisions.

On March 1, 2002, CMS published a final rule (67 FR 9556) that corrected technical errors that affected the amounts and factors used to determine the payment rates for services paid under the Medicare OPPS and corrected the uniform reduction to be applied to transitional pass-through payments for CY 2002 as published in the November 30, 2001 final rule. These corrections and the regulatory provisions that had been delayed became effective on April 1, 2002.

On May 9, 2002, CMS published a proposed rule (67 FR 31404) that proposed to revise the critera used for determinations of provider-based status, and replaced, the prior, mandatory application requirement with a voluntary attestation provision.

On August 1, 2002, CMS published a final rule (67 FR 49982) that revised the critera used for determinations of provider-based status, and replaced, the prior, mandatory application requirement with a voluntary attestation provision. For facilities or organizations treated as provider-based on October 1, 2000, these changes are effective for provider cost reporting periods beginning on or after July 1, 2003. For other facilities or organizations, these changes were effective on October 1, 2002.

On August 9, 2002, CMS published a proposed rule (67 FR 52092) that would revise the OPPS to implement applicable statutory requirements and changes arising from our continuing experience with this system. The changes are applicable to services furnished on or after January 1, 2003.

On May 4, 2005, CMS published a proposed rule (70 FR 23443).to clarify the critera used for determinations of provider-based status and the obligations of provider-based facilities.

On August 12 2005, CMS published a final rule (70 FR 47457) clarifying the critera used for determinations of provider-based status and the obligations of provider-based facilities.

B. Justification

1. Need and Legal Basis

Section 1833(t) of the Act, as added by section 4523 of the Balanced Budget Act of 1997 (the BBA) requires the Secretary to establish a prospective payment system (PPS) for hospital outpatient services. Successful implementation of an outpatient PPS requires that CMS distinguish facilities or organizations that function as departments of hospitals from those that are freestanding, so that CMS can determine which services should be

paid under the PPS. Information from the sections 413.65(b)(3) and (c) reports is needed to make these determinations. In addition, section 1866(b)(2) of the Act authorizes hospitals and other providers to impose deductible and coinsurance charges for facility services, but does not allow such charges by facilities or organizations which are not provider-based. Implementation of this provision requires that CMS have information from the required reports, so it can determine which facilities are provider-based.

2. Information Users

For sections 413.65(b)(3) and (c), CMS will use the information to determine whether a facility or organization acquired by a main provider should be treated as provider-based for Medicare certification, coverage, and payment purposes or whether a main provider has had a material change in its relationship to a provider-based facility or organization that affects the provider-based status of the facility or organization.

3. Improved Information Technology

These information collection requirements (ICR) do not lend themselves to improved information technology.

4. Duplication of Similar Information

These ICRs do not duplicate similar information.

5. Small Businesses

These requirements affect only small businesses and CMS has kept the requirements to the minimum necessary to implement the statute.

6. Less Frequent Collection

If this information is collected less frequently, the respondents would be out of compliance with the law.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice was published on or about September 22, 2006.

9. Payment/Gift To Respondent

There are no payments or gifts to the respondents.

10. Confidentiality

Data from this collection will be handled in accordance with established standards under the Freedom of Information and Right to Privacy Acts as set forth in 42 CFR 401 Subpart B.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimate

Section 413.24 Adequate cost data and cost finding.

Section 413.24(d)(6)(ii) states that a provider must develop detailed work papers showing the exact cost of the services (including overhead) provided to or by the free-standing entity and show those carved out costs as nonreimbursable cost centers in the provider's trial balance. While these information collection requirements are subject to the PRA, the burden associated with these requirements is captured under §§413.65(c)(1) and (c)(2) below.

Section 413.65 Requirements for a determination that a facility or an organization is a department of a provider or a provider-based entity.

Section 413.65(b)(3) states that a provider which is seeking a determination of provider-based status for a facility not located on the provider's campus must submit an attestation of compliance with applicable provider-based requirements and must supply documentation supporting its attestation at the time the attestation is made. Section 413.65(c) states that a main provider that has had one or more entities considered provider-based also may report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization.

The burden associated with this requirement is the time for the main provider to report its acquisition to CMS, furnish all information needed for a determination, report to CMS any material change in the relationship between it and any provider-based facility or organization, such as a change in ownership of the facility or organization or entry into a new or different management contract that could affect the provider-based status of the facility or organization**.** It is estimated that 105 main providers will take 10 hours for a total of 1,050 hours.

Section 413.65(d)(2)(v) states that medical records for patients treated in a facility or organization must be integrated and maintained into a unified retrieval system (or cross reference) of the main provider. The burden associated with this requirement is the time required for the main provider to maintain medical records in a unified retrieval system. While this requirement is subject to the PRA, CMS believes this requirement is a usual and customary business activity and the burden associated with this requirement is exempt from the PRA, as stipulated under 5 CFR 1320.3(b)(2) and (b)(3).

Section 413.65(e)(3) requires that if a determination of provider-based status is sought for a facility or organization that is not located within a 35-mile radius of the potential main provider, the facility or organization must demonstrate compliance with the location requirement in one of two other ways. The first option for meeting the location requirement is to show that the facility or organization is owned or operated by a hospital or CAH that has a disproportionate share adjustment (as determined under 42 CFR 412.106) greater than 11.75 percent or is described in 42 CFR 412.106(c)(2) implementing section 1886(e)(5)(F)(i)(II) of the Social Security Act and is either owned or operated by a unit of State or local government, is a public or nonprofit corporation that is formally granted governmental powers by a unit of State or local government, or is a private hospital that hss a contract with a State or local government that includes the operation of clinics located off the main campus of the hospital to assure access in a well-defined service area to health care services to low-income individuals who are not entitled to benefits under Medicare (or medical assistance under a Medicaid State plan). The other option for meeting the location requirement is for the facility to demonstrate a high level of integration with the main provider by showing that it meets all of the other provider-based criteria, and demonstrate that it serves the same patient population as the main provider, by submitting records showing that, during the 12-month period immediately preceding the first day of the month in which the application for provider-based status is filed with CMS, and for each subsequent 12-month period meet the requirements of paragraphs (e)(iii)(A), (B), or (C). While the information collection requirements listed below are subject to the PRA, the burden associated with these requirements is captured under §§413.65(b)(3) and (c).

Section 413.65(g)(7) states that when a Medicare beneficiary is treated in a hospital outpatient department or hospital-based entity, the hospital has a duty to notify the beneficiary, prior to the delivery of services, of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service).

The burden associated with this requirement is the time for the provider to disseminate information to each beneficiary of the beneficiary's potential financial liability (that is, a coinsurance liability for a facility visit as well as for the physician service). It is estimated that 750 providers will make on average 667 disclosures on an annual basis, at 3 minutes per disclosure, for a total annual burden of 25,013 hours.

Section 413.65(j)(5) requires that upon notice of denial of provider-based status sent to the provider by CMS, the notice will ask the provider to notify CMS in writing, within 30 days of the date the notice is issued, of whether the facility or organization (or, where applicable, the practitioners who staff the facility or organization) will be seeking to enroll and meet other requirements to bill for services in a free-standing facility. This requirement is exempt from the PRA as stipulated under 5 CFR 1320.4(a)(2).

Further, if the provider indicates that the facility or organization, or its practitioners, will be seeking to meet enrollment and other requirements for

billing for services in a free-standing facility, the facility or organization must submit a complete enrollment application and provide all other required information within 90 days after the date of notice; and the facility or organization, or its practitioners, furnish all other information needed by CMS to process the enrollment application and verify that other billing requirements are met.

The requirements and burden associated with the provider enrollment process are currently approved under the Office of Management & Budget (OMB) control number 0938-0685, with a current expiration date of March 30, 2009.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs.

14. Cost to Federal Government

For sections 413.65(b)(3) and (c), the Federal cost is based on the efforts expended by CMS to review the data submitted by the respondents. CMS estimates that cost to be $9402.75 (105 responses per year times 3 hours per response times the hourly rate of the reviewer, a GS12, step 1, salary of $26.53 per hour).

15. Program or Burden Changes

There has been one program and burden change. The previous version of CMS-R-240 included record collection requirements under 42 CFR 419.42(b) and (c) applicable to providers who elect to reduce coinsurance. That information collection was initiated so that CMS could identify providers who wish to reduce their coinsurance. Because the Outpatient Prospective Payment System (OPPS) PRICER was designed with edits to insure the reduced coinsurance was always at least 20% and since CMS can find the number of providers with reduced coinsurance in the Outpatient Provider Specific File (OPSF), that information collection document is no longer needed.

For sections 419.42(b) and (c), CMS estimated the Federal cost based on the efforts expended by the fiscal intermediaries to collect and review data from providers who elect to reduce coinsurance**.** CMS estimated about $4,126.50 for the Federal cost (50 respondents times 3 hours per response times the hourly rate of the reviewer, a GS-12 step 1 salary of $26.53 per hour).

The cost and burden estimate for this package has been reduced to reflect the elimination of the information collection under sections 419.42(b) and (c).

16. Publication and Tabulation Dates

CMS has no plans to publish, tabulate, or manipulate individual providers' reports received in compliance with proposed sections 413.65(c)(1) and (c)(2). However, it may be necessary to use data from these reports in completing studies or reviews of provider-based activity. Such studies or reviews could be needed for

internal CMS use, required by the Office of the Inspector General (OIG) or the U.S. General Accounting Office (GAO) investigators, or mandated by Congress. In any case, data from the reports would be handled in accordance with established standards under the Freedom of Information and Right to Privacy Acts as set forth in 42 CFR 401 Subpart B.

17. Expiration Date
These collection requirements do not lend themselves to an expiration date.

18. Certification Statement
There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods
These ICRs do not employ statistical methods.