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When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs.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).

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. Under this system, Medicare payment for hospital outpatient services included in the PPS is made at a predetermined, specific rate. 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. The provider-based rules are necessary so that CMS can distinguish facilities or organizations that function as department of hospitals from those that are freestanding, so that CMS can determine which services should be paid under the outpatient prospective payment system (OPPS), the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. Medicare payment and beneficiary coinsurance may be different when services are provided in a hospital outpatient department compared to a freestanding facility making these rules necessary. CMS implemented the OPPS on August 1, 2000.

The following history summarizes regulatory action related to the provider-based rules:

On August 3, 2000, CMS published an interim final rule with comment period (65 FR 47670) that corrected and clarified certain provider-based provisions included in the April 7, 2000 rule.

- On May 9, 2002, CMS published a proposed rule (67 FR 31404) that proposed to revise the criteria used for determinations of provider-based status, and replaced, the prior, mandatory application requirement with a voluntary attestation provision. This proposed rule was finalized on August 1, 2002 (67 FR 49982). 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.

- CMS made further clarification of the criteria used for determinations of provider-based status and the obligations of provider-based facilities in proposed and final regulation published on: May 4, 2005 (70 FR 23443), August 12, 2005 (70 FR 47457), May 22, 2009 (74 FR 24204), and August 27, 2009 (74 FR 43940).

- The May 22, 2009 proposed rule (74 FR 24204) and August 27, 2009 final rule (74 FR 43940) made a clinical diagnostic laboratory that is part of a critical access hospital (CAH) subject to the provider-based rules. The change was made because clinical diagnostic laboratory test furnished by CAHS are paid under reasonable costs and not under the clinical laboratory fee schedule. As there is a payment difference depending upon whether a clinical diagnostic laboratory service is furnished to a CAH outpatient or in any other setting, a clinical diagnostic laboratory that is part of a CAH must meet the provider-based rules for the CAH to be paid on the basis of reasonable costs for clinical diagnostic laboratory tests.

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 OPPS, the clinical laboratory fee schedule, or other payment provisions applicable to services furnished to hospital outpatients. 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 July 12, 2010, no comments were received.

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(a)(1)(ii) establishes a listing of specific facilities for which determinations for provider-based status for payment purposes are not made. As CMS removed certain CAH-based facilities from this list, such facilities must comply with provider-based rules to be paid as a CAH for outpatient services on a reasonable cost basis.

The burden associated with this requirement is the time for the main provider to report the facility's status to CMS and furnish all information needed for a determination. It is estimated that 155 main providers will take 10 hours for a total of 1550 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 has 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 $13,476 (155 responses per year times 3 hours per response times the hourly rate of the reviewer, a GS12, step 1, salary of $28.98 per hour).

15. Program or Burden Changes

There has been one program and burden change.

The previous version of CMS-R-240 referenced regulations at sections 413.65(b)(3) and (c) for facilities seeking provider-based status. These application requirements referenced criteria at 42 CFR 413.65(a)(1)(ii) that describes types of facilities excluded by CMS from provider-based determinations, and by extension are not required to comply with any provider-based regulations. CAHs previously did not have to meet the provider-based rules in order to be paid under reasonable costs for clinical diagnostic laboratory services. 413.65(a)(1)(ii)(G) has been amended to require clinical diagnostic laboratories operating as parts of critical access hospitals (CAHs) to comply with provider-based rules for the CAH to be paid under reasonable costs for clinical diagnostic laboratory tests. CAH may seek a provider-based determination under 413.65(a)(1)(ii)(G) beginning after October 1, 2010.

For revisions to section 413.65(a)(1)(ii)(G) CMS estimated the cost to the providers who submit a voluntary attestation seeking verification of provider-based status. We estimate the time associated with assembling and filing the attestation to their intermediaries to be 10 hours. We estimate total burden hours associated with this change to be 500 hours (that is 50 providers x 10 hours). When computed, assuming a current salary of $25 per hour plus 20 percent for fringe benefits ($30 per hour x 10 hours per hospital), the estimated cost of burden to file a voluntary attestation is $300 per hospital.

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.