Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

General Instructions

A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(I)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When Item 17 of the OMB Form 83-I is checked "Yes," Section C of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.

Specific Instructions

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When the Medicare statute was originally enacted, Medicare payment for hospital outpatient services was based on hospital specific costs.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 tests 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 reports required under sections 413.65(b)(3) and (c) 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. Use of Information Technology

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

4. Duplication of Efforts

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/Outside Consultation

The 60-day Federal Register Notice published on November 9, 2019(83FR56085) and the 30-day Federal Register Notice published on January 31, 2019(84FR734) with no comments received.

9. Payments/Gifts to Respondents

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 Estimates (Hours & Wages)

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. We believe this is reasonable as the information submitted by the applicant is typically information that the applicant already has with regard to their business. It is estimated that 250 main providers will take 10 hours per attestation. Therefore we have calculated the burden as follows: 250 responses x 10 hours per response = 2500 burden hours (annual). The time estimate for preparation of an attestation is based upon the professional judgment of staff members at the Centers for Medicare and Medicaid Services. We believe that an executive officer will be making the attestation because an executive officer is in the best position to have access to the business information required to make the attestation. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2017) at http://www.bls.gov/oes/current/oes_nat.htm# for Category 11-0000 for the position of Top Executives, the mean hourly wage for a top executive is $61.55. We have added 100 percent for fringe and overhead benefits, which calculates to $123.10 per hour. We estimate the total annual cost is $307,750.00 (2500 hours x $123.10 per hour).

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 1832 providers will make on average 7450 disclosures on an annual basis, at 3 minutes per disclosure (i.e. 0.05 hours). Therefore we have calculated the burden as follows: 13,648,400 responses x 0.05 hours per response = 682,420 burden hours (annual). The time estimate for preparation of an attestation is based upon the professional judgment of staff members at the Centers for Medicare and Medicaid Services. We believe this is reasonable as the information can be disseminated by providing the patient with a pre-printed written statement and we believe that most providers will provide the information to beneficiaries at the time of check-in through their receptionists. Based on the most recent Bureau of Labor and Statistics Occupational and Employment Data (May 2017) at http://www.bls.gov/oes/current/oes_nat.htm# for Category 43-4171 for the position of Receptionist and Information Clerks, the mean hourly wage for a receptionist and information clerk is $14.25. We have added 100 percent for fringe and overhead benefits, which calculates to $28.50 per hour. We estimate the total annual cost is $19,448,970.00 (682,420 hours x $28.50 per hour).

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 were approved under the Office of Management & Budget (OMB) control number 0938-0798, which expired February 28, 2017.

13. 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 $68,557.50 (750 responses per year times 3 hours per response times the hourly rate of the reviewer, a GS12, step 1, salary of $30.47 per hour).

15. Changes to Burden

We estimate that there will be an increase in the burden due to an increased estimation of the number of hours associated with this ICR. This increase is due to more refined estimates of the number of responses based on more recently available information. We estimate the time per response to be unchanged from the previous ICR. The previous ICR estimated that only 205 main providers would make attestations annually, however we now estimate that 250 providers will make attestations. This increases annual hours by 450 (10 hours per attestation x 45 additional attestations estimated). The previous ICR estimated that 750 providers would make an average of 667 disclosures per year. We currently estimate that 1832 providers will make on average 7450 disclosures on an annual basis. This increases annual hours by 657,407 (0.05 hours per disclosure x 13,148,150 additional disclosures estimated).

16. Publication/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

There is no collection data instrument used in the collection of this information. However, upon receiving OMB approval, CMS will publish a notice in the Federal Register to inform the public of both the approval as well as the 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.