Supporting Statement A

*Supporting Statement for Paperwork Reduction Act Submissions:*

*Electronic Submission of Medicare Graduate Medical Education (GME)*

*Affiliation Agreements (CMS-10326; OMB-0938-1111)*

1. **Background**

Existing regulations at § 413.75(b) permit hospitals that share residents to elect to form a Medicare GME affiliated group if they are in the same or contiguous urban or rural areas, if they are under common ownership, or if they are jointly listed as program sponsors or major participating institutions in the same program by the accrediting agency. The purpose of a Medicare GME affiliated group is to provide flexibility to hospitals in structuring rotations under an aggregate full time equivalent (FTE) resident cap when they share residents. The existing regulations at § 413.79(f)(1) specify that each hospital in a Medicare GME affiliated group must submit a Medicare GME affiliation agreement (as defined under § 413.75(b)) to the Medicare Administrative Contractor (MAC) servicing the hospital and send a copy to the Centers for Medicare and Medicaid Services’ (CMS) Central Office, no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect.

In the fiscal year (FY) 2011 Inpatient Prospective Payment System (IPPS) final rule, we finalized a policy to allow hospitals to electronically submit the copy of the affiliation agreement that is required to be sent to the CMS Central Office if the hospitals choose to participate in a Medicare GME affiliated group. The electronic submission process consists of an email mailbox where hospitals submit their Medicare GME affiliation agreements to the CMS Central Office no later than 11:59 p.m. on July 1 of the academic year for which the agreement is effective. The electronic affiliation agreement needs to be submitted either as a scanned copy or a Portable Document Format (PDF) version of a hard copy agreement or in another electronic format that cannot be subject to manipulation. This requirement also enables CMS to ensure that the agreements are signed and dated as required in the regulations at § 413.75. Each MAC continues to have the authority to specify its requirements for submission of the Medicare GME affiliation agreement by hospitals that are part of the affiliation.

No changes are being made to this package’s requirements or to any information collection reporting instruments or instructions. CMS is requesting OMB approval for this Reinstatement without change package.

1. ***Justification***

# Need and Legal Basis

Sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act establish limits on the number of allopathic and osteopathic FTE residents that hospitals may count for purposes of calculating direct GME payments and the indirect medical education (IME) adjustment. In addition, under the authority granted by section 1886(h)(4)(H)(ii) of the Act, the Secretary issued regulations on May 12, 1998 (63 FR 26358) to allow institutions that are members of the same Medicare GME affiliated group to elect to apply their direct GME and IME FTE resident caps based on the aggregate cap of all hospitals that are part of a Medicare GME affiliation group. Under those regulations, specified at § 413.79(f) for direct GME and at § 412.105(f)(1)(vi) for IME, hospitals that are part of the same Medicare GME affiliated group are permitted to adjust each hospital’s caps to reflect the rotation of residents among affiliated hospitals during an academic year. Under § 413.75(b), a Medicare GME affiliated group may be formed by two or more hospitals if: (1) The hospitals are located in the same urban or rural area or in a contiguous area and have a shared rotational arrangement as specified at § 413.79(f)(2); (2) the hospitals are not located in the same or in a contiguous area, but have a shared rotational arrangement and they are jointly listed as the sponsor, primary clinical site, or major participating institution for one or more programs as these terms are used in the most recent publication of the *Graduate Medical Education Directory,* or as the sponsor or is listed under ‘‘affiliations and outside rotations’’ for one or more programs in *Opportunities, Directory of Osteopathic Post-Doctoral Education Programs;* or (3) effective beginning July 1, 2003, two or more hospitals are under common ownership and have a shared rotational arrangement under § 413.79(f)(2).

# Information Users

CMS will use the information contained in electronic affiliation agreements as documentation of the existence of Medicare GME affiliations, and to verify that the affiliations being formed by teaching hospitals for the purposes of sharing their Medicare GME FTE cap slots are valid according to CMS regulations. CMS will also use these affiliation agreements as reference materials when potential issues involving specific affiliations arise. While we have used hard copies of affiliation agreements for those same purposes in the past, we implemented this electronic submission process in order to expedite and ease the process of retrieving, analyzing and evaluating affiliation agreements.

# Use of Information Technology

We have allowed this collection of information to be completed electronically since FY2011, which includes permission for hospitals to submit the affiliation agreement information electronically. Prior to allowing electronic submissions of Medicare GME affiliation agreements, CMS only accepted signed hard copies of Medicare GME affiliation agreements received through the mail. Facsimile (FAX) and other electronic submissions of affiliation agreements were not acceptable means of transmission of affiliation agreements to CMS Central Office. We implemented this electronic submission process because we had received numerous inquiries from hospitals regarding the possibility of submitting the Medicare GME affiliation agreement electronically in the years prior to the implementation of the process. The increasing frequency of those inquiries and our concerns regarding environmental and paperwork reduction prompted us to reconsider our procedure for the submission of Medicare GME affiliation agreements to the CMS Central Office. Accordingly, we changed our policy to provide for electronic submission of the affiliation agreement to the CMS Central Office.

# Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

1. Small Businesses

This information collection does not affect small businesses.

# Less Frequent Collection

Our regulations state that hospitals that want to share Medicare GME FTE cap slots must submit an affiliation agreement to the CMS FI or MAC servicing the hospital, and send a copy to the CMS Central Office, no later than July 1 of the residency program year during which the Medicare GME affiliation agreement will be in effect. Therefore, this information collection must occur annually if a hospital chooses to participate in a Medicare GME affiliated group.

# Special Circumstances

There are no special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

* Report information to the agency more often than quarterly;
* Prepare a written response to a collection of information in fewer than 30 days after receipt of

it;

* Submit more than an original and two copies of any document;
* Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
* Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
* Use a statistical data classification that has not been reviewed and approved by OMB;
* Include a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or
* Submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

1. Federal Register/Outside Consultation

The 60-day Federal Register notice published to the Federal Register 2/18/2021 (86 FR 10084)

No comments were received during the comment period.

The 30-day Federal Register notice published to the Federal Register 4/28/2021 (86 FR 22438)

# Payments/Gifts to Respondents

No gifts or payments are provided to respondents for their participation.

Submitting copies of their affiliation agreements to CMS and the MACs, allows teaching hospitals with GME programs to share a combined FTE resident cap, and to reapportion the FTE slots among themselves. This could, for example, support programs where residents rotate through experiences at more than one hospital.

1. Confidentiality

We do not pledge confidentiality in reference to this collection of information.

1. Sensitive Questions

There are no sensitive questions associated with this collection.

12. Estimates (Hours & Wages)

The burden associated with this requirement is the time and effort that would be required for a new hospital to develop and submit the Medicare GME affiliation agreement, to submit the agreement to its MAC, and to submit a copy to CMS. We anticipate receiving between 100 and 150 GME affiliation agreements annually. For the purpose of mathematically estimating the total annual burden of our information collection request, we chose 125, as the midpoint between 100 and 150 GME affiliation agreements received annually. We estimate that it will take 1 hour (60 minutes) for a hospital to develop a GME affiliation agreement or to follow the format provided by CMS. Therefore, the total annual burden associated with developing the affiliation agreement is 125 hours (125 agreements x 1 hour).

We estimate that it will take each hospital an additional 15 minutes to submit a hard copy or an electronic copy of the affiliation agreement to its MAC. Accordingly, the total annual burden associated with submitting a hard copy of the affiliation agreement is 31 hours (125 agreements x 0.25 hours).

Finally, we estimate that it will take each hospital 5 minutes to submit an electronic copy of its GME affiliation agreement to CMS. The total annual burden associated with submitting the agreement electronically would therefore be 10 hours (125 agreements x 0.08 hours). Please note that these estimates are based on a hospital developing its affiliation agreement in the form of the two-page sample agreement that CMS provides to hospitals upon request. Some facilities submit additional information along with their affiliation agreements that is not required. In sum, the total annual burden associated with all of the requirements in this section is 166 hours (125 hours + 31 hours + 10 hours).

The information for the various items that are included in affiliation agreements are usually compiled by a hospital’s financial staff. Based on wage data from the 2019 Bureau of Labor Statistics for the Occupation Code 13-2011: Accountants and Auditors, we are using an average salary of $ 38.23/hour to calculate the cost of developing and submitting an affiliation agreement. We also are including 100% of that salary for fringe benefits, which results in a total average salary of $76.46/hour. The cost of developing and submitting one affiliation agreement would therefore be $12,692.36 ($76.46 x 166 hours). <https://www.bls.gov/oes/current/oes132011.htm>

13. Capital Costs

We estimate that there are minimal to no capital costs to respondents or record keepers that would result from this collection of information.

14. Cost to Federal Government

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As a result of implementing this electronic submission process for Medicare GME affiliation agreements, we estimate that there will be an annual cost of $ 6,955.20 to the Federal Government. We estimate that Central Office staff will spend approximately 120 hours over the course of each year sorting and reviewing submitted Medicare GME affiliation agreements at the cost of the 2021 Washington-Baltimore GS-13, Step 6 salary of $57.96/hour ($57.96 x 120 hours = $ 6,955.20). <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary>tables/pdf/2021/DCB\_h.pdf

# 15. Changes to Burden

No changes are being made to this package’s requirements or to any information collection reporting instruments or instructions and hourly burden will remain the same. As a result of updating the Bureau of Labor Statistics wage data for the Occupation Code 132011: Accountants and Auditors to reflect 2019 data, the burden estimate changed such that the cost of developing and submitting one affiliation agreement increased from $12,247.48 to $12,692.36. The Bureau of Labor Statistics wage data previously used was from 2018.

1. Publication/Tabulation Dates

No publication or tabulation of the data collected is expected.

1. Expiration Date

The expiration is displayed on the top, right corner of the first page of the form.

1. Certification Statement

There are no exceptions to the certification statement.