Supporting Statement for the
Information Collection Requirements in 42 CFR
412.105(f) and 42 CFR 413.75(d)
Indirect Medical Education and Direct Graduate Medical Education
CMS-R-64, OMB 0938-0456

A. BACKGROUND

Section 1886(d)(5)(B) of the Social Security Act requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413, sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment for the costs of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2018, the estimated Medicare program payments for indirect medical education (IME) costs was $6.4 billion. Medicare program payment for direct graduate medical education (GME) is also based upon the number of FTE-IRs that work at a hospital. In FY 2018, the estimated Medicare program payments for GME costs was $3.1 billion.

Since it is important to accurately count the number of IRs FTEs working at each hospital, original approval was obtained from the Office of Management and Budget (OMB) in 1985 to collect the IR information required in 42 CFR 412.105(f), under OMB control number 0938- 0456. On September 30, 2016, OMB extended its approval for the continuation of these requirements until May 30, 2020.

At this time, we are seeking an extension of OMB's currently approved collection of information required in 42 CFR 412.105(f), under OMB control number 0938-0456.

B. JUSTIFICATION

1. Need and Legal Basis

During the first 3 months of PPS, only IRs that were employed by a hospital could be included in the IME calculation. Accordingly, a hospital's IR FTE count could be determined and verified from readily available accounting data such as payroll records.

With cost reporting periods beginning on or after January 1, 1984, hospitals were permitted to include IRs in their IME calculation that worked at the hospital but were employed by an organization with which it had a long-standing relationship. While this was an important change, it did not present any special problems in counting and verifying the number of IRs FTE at each hospital. However, section 1886 (d)(5)(B)(iii) of the Act also provides for all IRs in approved programs working at a hospital to be included in the IR calculation regardless of the entity which employs them.

This change was effective for cost reporting periods beginning on or after October 1, 1984. It necessitates the collection of specific data from the hospitals in order to properly count IRs FTE because data such as payroll records could no longer be used to document IR services. This is because many IRs employed by only one entity routinely work at several different hospitals during an academic year.

42 CFR 412.105(f) which was previously codified at 42 CFR412.105(g) provides the rules for counting IRs pursuant to the amendments enacted by the Deficit Reduction Act of 1984 (Public Law 98-369). In part, these rules explain that no IR is counted as more than one FTE, regardless of the number of hospitals in which he or she may be providing service. In addition, 42 CFR 412.105(f) requires hospitals to submit an annual report which lists each IR that worked at the facility. The listing reflects the hospital's determination of its FTE-IR count, and it serves as the basis for CMS to verify the accuracy of the count as well as ensuring that no IR is counted as more than one FTE.

To implement the data collection requirements of 42 CFR 412.105(f) (previously codified at 42 CFR 405.477 and at 42 CFR 412.118), a Notice of New System of Records was published in the Federal Register on February 15, 1985 (50 FR 6335), pursuant to the Privacy Act of 1974. This notice explained that hospitals would be required to submit quarterly reports containing the actual number of hours worked by each IR at the hospital during each month. However, this reporting requirement was not implemented because of the record keeping burden it placed on hospitals. Based upon comments received on the notice, and an analysis of graduate teaching programs, the reporting requirements were changed to a once-a-year, one-day count. In general, the report hospitals needed to submit was based upon a census of IRs working at the hospital on September 1 of each year.

The propriety of this single date method of counting IRs as being reflective of the actual intensity of IR services at a hospital throughout a cost reporting period is predicated on the fact that there is a general consistency in IR rotations among hospitals.

Effective with cost reporting periods beginning on or after July 1, 1991, the number of IRs included in the IME calculation is based upon the total time necessary to fill an IR slot. This means that the amount of time spent by each IR at each PPS hospital where that individual may work during the providers' cost reporting periods must be determined. While this methodology is significantly more detailed than the one-day count, because it requires a definitive tracking and measurement of IR time, it is superior to the one-day count.
Specifically, the new methodology provides for a more precise measurement of IR services by capturing fluctuations in the number of IRs working in the hospitals throughout their cost reporting periods. In addition, there is a greater potential for abuse using the one-day count methodology than there is under the new methodology. For example, an IR may work at a PPS hospital for a portion of September 1, and be reported by that hospital for IME. However, the IR may also have worked at another hospital on September 1, which will also report the IR for the calculation of its IME payment. These situations, if undetected, result in duplicate program payments.

42 CFR 412.105(f) provides the rules for counting IRs effective with cost reporting periods beginning on or after July 1, 1991. In part, these rules explain that no IR may be counted as more than one FTE. In addition, if a resident is assigned to more than one hospital, the individual counts as a partial FTE based upon the portion of time worked in the portion of the hospital subject to PPS, to the total time worked at all hospitals. A part-time resident is counted as a partial FTE based upon the amount of time worked in the portion of a hospital subject to PPS, to the total time necessary to fill a full-time IR slot.

To re-implement the data collection requirements of 42 CFR 412.105(f) and to implement similar requirements of 42 CFR 413.86(i), a Notice of Modified or Altered System of Records (SOR)--Intern and Resident Information System(IRIS) was prepared pursuant to the Privacy Act of 1974; it was originally published in the Federal Register on Tuesday, July 23, 2002. This notice was revised several years later to include 42 CFR 413.75(d) which was originally codified at 42 CFR 413.86(i), and it was published in the Federal Register on Monday, December 10, 2007.

2. Information Users

The information collected on IRs is used by Part A Medicare Administrative Contractors (MAC) to verify the number of IRs FTE used in the calculation of Medicare payments for IME and GME.

The IR data submitted by the hospitals to the MACs is uploaded into CMS' Intern and Resident Information System (IRIS) database to identify duplicate FTEs reported for any IR.
The identification of duplicate IRs is necessary to ensure that no IR is counted more than one FTE. The workload associated with these processes involves approximately 123,420 IRs and 1,245 teaching hospitals.

The MACs use the information collected on IRs to ensure that all program payments for IME and GME are accurate, and are in accordance with Medicare regulations. The IR data submitted by the hospitals to the MACs are used to audit the Medicare cost reports filed by the hospitals.

3. Improved Information Technology

The existing IRIS DBF file format will be retired and replaced by a redesigned XML file format. The new format will capture a few additional fields and will organize the data inside a normalized data structure but otherwise generally captures the same fields as the legacy DBF format and maintains the same core data model built around resident records and assignment records (See IRIS New XML Summary attachment for a summary of changes).

As part of this change, the IRISv3 and IRISEDv3 applications will also be retired. For the new XML format CMS will publicly release all the technical specifications and documentation needed to create an IRIS file, but will not release a replacement for the IRISv3/IRISEDv3 applications for creating IRIS files. Instead, Providers will be encouraged to use IRIS vendor software in order to prepare their IRIS submissions. The process by which IRIS files are submitted will stay the same. Providers will continue to submit their IRIS submission to their MAC alongside their cost report.

4. Duplication of Similar Information

The American Medical Association (AMA) and the Association of American Medical Colleges (AAMC) were contacted because they also monitor IR activities. However, it was determined that they do not collect all of the information needed to calculate payments for IME and GME in accordance with Medicare regulations. Accordingly, the data collection does not result in a duplication of effort.
In addition, both 42 CFR 412.105, which pertains to IME and 42 CFR 413.75, which pertains to GME, require hospitals to report much of the same information on IRs; most of the data required by these rules have been consolidated for IME and GME in IRIS program. Accordingly, the burden associated with these rules has been reduced, because hospitals will only be required to submit one IR data report per year.

5. Small Business

These requirements do not significantly impact small business.

6. Less Frequent Collection

The information is submitted only once a year, at the same time that the hospitals submit their Medicare cost reports. The data collection supports the hospital's claim for reimbursement for IME and GME, and is the basis for verifying the accuracy of this claim through the cost report audit and settlement process. Accordingly, if this information were received less frequently than the Medicare cost report it supports, the settlement process would be disrupted. This means that the MACs may need to perform costly reopenings at a later date and, depending upon the circumstances, result in outstanding overpayments or underpayments to the hospitals.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Register notice was published to the Federal Register April 8, 2019 (84 FR 13929) Two comments were received and responses to the comments are included in the PRA package.

The 30-day Federal Register notice was published to the Federal Register May 14, 2020 (85 FR 28948) No comments were received.

9. Payment/Gift to Respondent

There is no payment or gift made to any respondent.

10. Confidentiality

The data collected on IRs is protected under Privacy Act System Number 09-70-0524, Intern and Resident Information System, HHS, CMS, Office of Financial Management, Federal Register/ Volume 72/ No. 236/ Monday, December 10, 2007, pages 69691-69696.

11. Sensitive Questions

There are no questions of a sensitive nature involved in the IR data collection.

12. Burden Estimate (Total Hours & Wages)

The burden associated with the information collection is based upon the time attributable to each hospital in maintaining minimal records, and preparing and forwarding the annual report to the MAC.

In order to determine a hospital's IR count in accordance with the regulations, hospitals must report the name, social security number, and dates that each IR was assigned to the hospital, and the dates they were assigned to other hospitals or other freestanding providers and non- provider settings during the cost reporting period. In addition, the hospitals must report each IR's specialty, and the portion of total time necessary to fill the residency slot in which the IRs worked, either in an area of the hospital subject to PPS, or the hospital's outpatient department.

It is estimated that each hospital will spend 2 hours preparing the information for the IR collection. Burden is calculated as follows:

1,245 PPS teaching hospitals which participate in approved medical education programs multiplied by 2 hours per report equals 2,490 burden hours.

Cost to Respondents:

Total costs for all hospitals for annual reporting is estimated at $166,033 per year as follows:
The 2,490 burden hours multiplied by the composite rate of $66.68 per hour to account for $33.34 hourly wage and $33.34 (100% of hourly wage) for estimated benefits and overheads. The average hourly wage for an accountant is $33.34 according the U.S. Dept. of Labor, Bureau of Labor Statistics website https://www.bls.gov/oes/current/oes132011.htm .

The new IRIS XML format will require hospitals to use vendor software to report their IR FTEs. The free dbase Irisv3 will no longer be available. Over 90% of hospitals currently use vendor software to prepare their IRIS IR FTEs because the dbase IrisV3 is not compatible with modern operating systems.

Total Cost to Teaching Hospitals:

Wage and Benefits Costs ($66.68 x 2,490)	166,033	
Vendor Software Costs		
(Average vendor software cost of $700 x 2490)	1,743,000	
Total Costs to Hospitals		**1,909,033**
Less 2016 Estimated Benefits and Overhead Costs		(89,640)
Less the of Hospitals Currently Using Vendor Software (2,490 x 90% = 2,241 x 700)		(**1,568,700)**
Adjusted Variance between 2019 and 2016 Estimated Burden		**250,693**

The variance between the current estimated burdens compared to the estimated costs from 2016 approval is due to the following:

The 2016 estimated burden did not account for benefits and overhead which would have been $89,640 (100% of hourly rate = $36 multiplied by 2490).

The 2016 estimated burden failed to account for the costs of about 90% of hospital that currently use vendor software because the current Dbase IRIS program is not compatible with modern operating systems.

13. Capital Costs

There are no capital and startup costs or operation and maintenance costs associated with this collection.

14. Cost to Federal Government

Federal government cost for data entry and processing is estimated to be $6,652 per year. This estimate includes the time and costs of a computer specialist/business owner for administering the IRIS system, and peripheral costs (computer usage/programming, data transmission/storage, printouts, etc.), as follows:

Computer Specialist/Business Owner (116 hours at	
$49 per hour)	$5,684
Peripheral Costs	968
Total Federal Government Costs	$6,652

15. Program Changes/Adjustments

The existing IRIS DBF file format will be retired and replaced by a redesigned XML file format. The new format will capture a few additional fields and will organize the data inside a normalized data structure but otherwise generally captures the same fields as the legacy DBF format and maintains the same core data model built around resident records and assignment records. Except for one field being removed, the new XML format will contain the same fields as the old DBF format plus new fields explained further in the Format Summary document.

As part of this change, the IRISv3 and IRISEDv3 applications will also be retired. For the new XML format CMS will publicly release all the technical specifications and documentation needed to create an IRIS file, but will not release a replacement for the IRISv3/IRISEDv3 applications for creating IRIS files.

16. Publication Data

There are no plans to publish the information collected under this submission.

17. Expiration Date

Please refer to the PRA disclosure statement at the bottom of the additional documents within this package.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

Not applicable.