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

A. BACKGROUND

Section 1886(d)(5)(B) of the Social Security Act (Attachment 1) 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 (Attachment 2) implement section 1886(d) of the Act by establishing the methodology for Medicare payment of the cost 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 In Federal fiscal year (FY) 2005, the estimated Medicare program payments for indirect medical education (IME) costs amounted to \$5.99 billion (the \$1.5 billion amount reported for FY 2002 is understated; this amount should have been reported as \$5.55 billion). Medicare program payments for direct graduate medical education (GME) are also based upon the number of FTE-IRs that work at a hospital. In FY 2005, the estimated Medicare program payments for GME costs amounted to \$2.21 billion.

Since it is important to accurately count the number of FTE-IRs 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. In November 2003, OMB extended its approval for the continuation of these requirements until November 30, 2006.

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

B. JUSTIFICATION

1. Need and Legal Basis

During the first 3 months of PPS only those IRs that were

employed by a hospital could be included in the IME calculation. Accordingly, a hospital's FTE-IR 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 FTE-IRs at each hospital. However, in 1984, section 2307(b) of the Deficit Reduction Act (Pub. L. 98-369, Attachment 3) provided 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, which was effective for cost reporting periods beginning on or after October 1, 1984, necessitates that specific data be collected from the hospitals in order to properly count FTE-IRs, because data such as payroll records could no longer be used to document IR services. This is because many IRs are actually employed by only one entity, but routinely work at several different hospitals during an academic year.

42 CFR 412.105(f) (Attachment 4) which was previously codified at 42 CFR 412.105(g) provides the rules for counting IRs pursuant to the amendments enacted by Pub. L. 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. While the listing reflects the hospital's determination of its FTE-IR count, 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 (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 recordkeeping 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 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 implement the data collection requirements of 42 CFR 412.105(f), 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. This notice received the necessary approvals and was published in the Federal Register on Tuesday, July 23, 2002 (Attachment 5). In effect, the Notice explains that this SOR will be modified to cite the data collection requirements of 42 CFR 412.105(f) and 42 CFR 413.75(d) which was previously codified at 42 CFR 413.86(i) (Attachment 6); the latter citation pertains to IR information that is needed to determine Medicare payments 42 CFR 413.75 requires hospitals to report much for GME. of the same information on IRs that is required by 42 CFR 412.105(f). Under section 9202(h) of Public Law 99-272 (Attachment 7), the information required by 42 CFR 413.75 is not subject to the requirements of the Paperwork Burden Reduction Act of 1995. In addition, the security classification previously reported as "None" for this SOR will be reclassified as "Level Three Privacy Act Sensitive" in regard to the protection of individual-specific information in the IR data.

2. Information Users

The information collected on IRs is used by the Medicare Part A fiscal intermediaries (FI) to audit the number of IRs used in the calculation of Medicare program payments for IME as well as GME.

The IR data collected from the hospitals is processed through computers at FIs to identify any duplicated time based upon the accumulated time of each individual that worked at one or more hospitals. The identification of duplicate IRs is necessary to ensure that no IR is counted more than once. The workload associated with these processes involves approximately 105,000 IRs and 1,215 teaching hospitals.

The FIs use the information collected on IRs to help ensure that all program payments for IME and GME are based upon an accurate number of FTE-IRs, determined in accordance with Medicare regulations. The IR data submitted by the hospitals are used by the FIs during their audits of the providers' cost reports. The audit procedures help assure that the information reported was correct, and that IRs who should not have been reported by the hospitals (or portions of the IRs' time) are not included in the FTE count. The FIs also use reports of duplicate IRs to prevent improper payment for IME and GME. If it is determined that a hospital has been inappropriately reimbursed for IME and/or

GME, immediate corrective action is taken.

3. Improved Information Technology

In accordance with the provisions of the Notice of Modified or Altered SOR--IRIS published in the Federal Register on July 23, 2002, hospitals will report the required information into two files on an IRIS diskette by using their copy of CMS' IRIS data collection program currently called IRISV3 (Attachment 8, Page 5-1). Thus there is no hard copy or paper reporting of the information for burden to be associated with. The burden associated with computer input generation is greatly reduced by a download feature in IRISV3 which allows hospitals to electronically import their IR data files created outside of the IRISV3 program into IRISV3 (Attachment 8, Pages 4-14,15).

IRISV3, a DOS-based application, is an improved version of CMS' former IRIS data collection program called IRIS95. This program incorporates recommendations made by an IRIS workgroup of hospital, FI and CMS participants during May 1997 for reducing the electronic reporting burden of IRIS95 on hospital administrators. These recommendations included the reprogramming of IRIS95 for Y2K certification, elimination of redundant questions on foreign medical school graduates, and reproduction of IRISV3 data entry instructions within the IRISV3 program (the Help screens and code tables) in the IRISV3 Operating Instructions. IRISV3 is currently operable in Windows-based computers that are capable of running DOS programs.

Hospitals may also create their own IRIS diskettes with IR data files that are not edited by IRISV3. These diskettes are acceptable upon passing all IRIS system edits in IRISEDV3 (Attachment 9, pages 5-9), a DOS-based application that was developed by CO for editing IR data files on IRIS diskettes. CO distributed this application to hospitals and FIs in June 2002 to ensure that hospital created IRIS diskettes with unedited IR data pass all IRIS system edits. IRISEDV3 is also currently operable in Windows-based computers that are capable of running DOS programs. Both of these applications are currently available at: http://cms.hhs.gov/IRIS.

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 IRISV3. 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 FIs 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 published on August 14, 2006.

Four individuals were contacted to discuss the availability of data, frequency of collection, and clarity of instructions and reporting format. In addition, arrangements were made with the AAMC to test IRISV3 and IRISV3 Operating Instructions for collecting IR data; similar arrangements were made with Johns Hopkins Hospital to test IRISEDV3 for editing IR data. Disclosure of

information obtained from the data collection was published

in the Federal Register on July 23, 2002, as part of the Notice of Modified or Altered SOR--IRIS.

The names and phone numbers of the individuals contacted are as follows:

American Medical Association Derek Smart, Division of Survey & Data Resources, 312-464-4825

Association of American Medical Colleges Jennifer Faerberg, Office of Health Care Affairs, 202-862-6221

Ernst & Young, LLP David Andrzejewski, Senior Consultant, 314-290-1055

Johns Hopkins Hospital Matthew E. Myers, Department of Medical Affairs, 410-955-6771

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, <u>Federal Register</u>/ Volume 67/ No. 141/ Tuesday, July 23, 2002, pages 48189-48194.

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 FI.

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:

1,215 PPS hospitals which participate in approved medical education programs multiplied by 2 hours per report equals 2,430 burden hours.

Cost to Respondents:

Total costs for all hospitals for annual reporting is estimated at \$99,630 per year as follows:

2,430 burden hours multiplied by the standard rate of \$41 per hour (GS-13, Step 4) equals \$99,630.

13. <u>Capital Costs</u>

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 \$33,215 per year. This estimate includes the time and costs of a computer specialist for administering the IRIS system, and peripheral costs (computer usage/programming, data transmission/storage, printouts, etc.), as follows:

Computer Specialist (½ year or 695 hours at \$41 per hour) \$28,495 Peripheral Costs 4,720 Total Federal Government Costs \$33,215

15. Program Changes/Adjustments

The decrease in burden from 2,450 hours as shown on CMS' previous Request for OMB Review, to 2,430 hours shown above, directly reflects a decrease in the number of

hospitals.

16. Publication Data

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

17. Expiration Date

We are not seeking approval for the non-display of the expiration date for the information system.

18. Certification Statement

There are no exceptions to the certification statement.

C. <u>Collection Of Information Employing Statistical Methods</u>

Not applicable.