Supporting Statement for Rehabilitation Unit/Hospital Criteria Worksheet Forms CMS-437A and CMS-437B (OMB NO. 0938-0986)

A. BACKGROUND

This supporting statement requests Office of Management and Budget (OMB) approval for the following three forms:

- Rehabilitation Unit Criteria Work Sheet (CMS-437A)
- Rehabilitation Hospital Criteria Work Sheet (CMS-437B)

The above-stated worksheets represent requirements in current Federal regulations at 42 CFR Parts §412.20 through §412.29 for specialty hospitals and specialty distinct-part units of hospitals to be exempt from the Inpatient Prospective Payment System (IPPS). These specialty hospitals and specialty distinct part units include Inpatient Rehabilitation Facility (IRF) distinct-part units in hospitals and freestanding inpatient rehabilitation hospitals.

Inpatient Rehabilitation Facilities (IRFs) are free standing rehabilitation hospitals and rehabilitation units in an acute care hospital. They provide an intensive rehabilitation program. Patients who are admitted to an IRF must be able to tolerate three hours of intense rehabilitation services per day. IRFs must meet the 60 percent rule, which means that 60 percent of the IRF's patient population must receive intensive rehabilitation services for one of 13 medical conditions during the IRF's previous cost reporting year. In order to be paid under the IRF PPS, an IRF must submit an Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI) for each patient. The IRF-PAI is the patient assessment instrument currently utilized by CMS for the computation of Medicare payment. Excluded IRFs are paid under the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) as provided under section 1886(j) of the Social Security Act effective January 1, 2002.

IRF units within a hospital as well as freestanding IRF hospitals may be excluded from reimbursement under the Inpatient Prospective Payment System (IPPS) which determines Medicare payment for operating costs and capital-related costs of inpatient hospital services for the purpose of receiving reimbursement under another specialized CMS payment systems or schedule. The CMS regulations at 42 CFR §412.20 through §412.29 describe the criteria under which these specialty hospitals and specialty distinct-part hospital units are excluded from the IPPS.

These IRFs must attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. Additionally, IRFs must re-attest to meeting the exclusion criteria once every three years thereafter.

Forms CMS-437A and CMS-437B are used by the IRFs to attest to meeting the IPPS exclusion criteria at 42 CFR §412.20 to §412.29. Form CMS-437A is to be used by IRFs that are distinct-part units within a hospital. Form CMS-437B is to be used by IRFs and IPFs that are a hospitals within a hospital or exist as freestanding hospitals.

B. JUSTIFICATION

1. Need and Legal Basis

Certain specialty hospitals and hospital specialty distinct-part units may be excluded from the Inpatient Medicare Prospective Payment System (IPPS) and be paid at a different rate. These specialty hospitals and distinct-part units of hospitals include Inpatient Rehabilitation Facilities (IRFs).

The exclusion of these specialty hospitals and distinct-part specialty units of hospitals is not optional on the part of the provider. Exclusion from the IPPS permits the specialty hospitals and distinct-part specialty units of hospitals to be paid at a different payment rate which reflects the cost of providing specialized services. Excluded Inpatient Rehabilitation Facilities (IRFs) are paid under the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS) as provided under section 1886(j) of the Social Security Act.

The criteria for IPPS exclusion are defined in regulation at 42 CFR §412.20 through §412.29 and discussed in section 3100 of the CMS State Operations Manual (SOM). These regulations have provisions that are specific to the above-stated specialty hospitals and distinct-part specialty units of hospitals. Exclusion criteria that are specific to IRFs are located at §412.29 and provisions specific to IPFs are located in §412.27.

Initially, these criteria were developed into a worksheet that are used by State Survey Agencies (SAs) and hospitals to assess IRFs for compliance with the IPPS exclusion requirements. The CMS-437A was the worksheet used by the SA surveyors to assess inpatient rehabilitation units and long term care units within a hospital. The CMS-437B was the worksheet used by the SA surveyors to assess the inpatient rehabilitation hospitals. The SA surveyors used these worksheets when conducting onsite IPPS exclusion surveys to verify that the IPPS exclusion criteria were met by the IRF units and hospitals. This assessment was completed prior to placing an IRF into excluded status.

However, due to significant budget cuts, beginning on November 5, 2007, CMS suspended the requirement for onsite IPPS exclusion surveys and instead began allowing the specialty hospitals and distinct-part specialty units to self-attest to meeting the IPPS exclusion criteria. (See S&C 08-03, 11/05/2007). As a result, instead of having the SA perform an IPPS exclusion survey, the IRFs units and hospitals were required to complete forms CMS-437A and CMS-437B (as

applicable) annually as a self- attestation indicating they continued to meet the IPPS exclusion criteria. The IRF would complete and submit the required CMS-437 form to the CMS Regional Offices through their respective State Survey Agency. The attestation procedures are defined in the State Operations Manual (SOM) Section 3100 (CMS Pub 100-07).

In 2012, CMS changed the frequency of self-attestation for IRFs from annually to once every three years (See S&C 13-04-IRF).

2. <u>Information Users</u>

For first time verification requests for exclusion from IPPS, an IRF hospital or IRF unit must notify the RO, servicing the State in which it is located, that it intends to seek excluded status from the IPPS. Currently, all new IRFs must provide written certification that the inpatient population it intends to serve will meet the requirements of the 60% rule for IPPS exclusion criteria for IRFs (42 CFR 412.29(b)(2). They must also complete the form CMS-437A if they are a rehabilitation unit or a form CMS-437B if they are a rehabilitation hospital. This information is submitted to the State Survey Agency no later than 5 months before the date the hospital/unit would become subject to IRF-PPS.

IRFs already excluded from IPPS will be provided a copy of the appropriate CMS-437 Worksheet at least 120 days prior to the beginning of its cost reporting period. Hospital/unit officials complete and sign an attestation statement and return the appropriate CMS-437A or CMS-437B to the CMS RO through the SA. The Medicare Administrative Contractor (MAC) will continue to verify, on an annual basis, compliance with the 60 percent rule for rehabilitation hospitals and rehabilitation units through a sample of medical records and the SA will verify the medical director requirement. The SA must transmit the worksheets to the RO at least 60 days prior to the end of the rehabilitation hospital's/unit's cost reporting period.

This information will be reviewed by the CMS RO when determining exclusion from the IPPS. IRF hospitals and units that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated once every three years to determine whether they continue to meet the exclusion criteria.

SA surveyors will periodically conduct onsite verification of the exclusion criteria. These are conducted when the SA is onsite conducting a complaint survey or if the facility is selected for survey as part of the SA's annual 5 percent validation sample.

3. <u>Use of Information Technology</u>

The appropriate form CMS-437, CMS-437A or CMS-437B is either mailed to the facility from the SA or the provider can obtain a copy in PDF format from the CMS website.

At this time, the CMS-437A and CMS-437B forms are not set up for electronic submission. If CMS decides to convert these forms to an electronic submission format, we will submit another PRA package notifying OMB of our intent to do so.

4. <u>Duplication</u>

There is no duplication of information. The information collected is the minimum required under the regulations at 42 CFR \$412.20 - \$412.29. The information is separate from the Conditions of Participation that are assessed during a routine survey.

5. Small Business

This information is required by regulation. It is the minimum necessary and cannot be further reduced for small businesses.

6. <u>Less Frequent Collection</u>

An IRF must self-attest to the attestation requirement prior to being placed in excluded status and periodically thereafter. CMS reduced the frequency of collection for this information for IRFs in 2012 from yearly to once every three years. The re-verification process is completed to ensure that the exclusion criteria, e.g., personnel, services, number of admissions/discharges, and full-time or part-time director, number of beds, continue to be met. These areas may be subject to frequent change in the hospital environment.

7. <u>Special Circumstances</u>

There are no special circumstances associated with this collection. This collection is consistent with the guidelines in 5 CFR §1320.6.

8. Federal Register and Outside Consultations

The 60-day Federal Register notice published on March 15, 2019 (84 FR 9526). There were no public comments received. The 30-day Federal Register notice published June 26, 2019 (84 FR 30122).

9. Payment/Gifts to Respondent

There are no payments or gifts involved in this information collection.

10. Confidentiality

Information collected will be utilized by CMS and its agents for certification and enforcement actions. This information is publicly disclosable. Any identifiable data subject to the Privacy Act is deleted prior to disclosure.

11. Sensitive Questions

There are no questions of a sensitive nature on the form.

12. Estimate of Burden (Hours and Wages)

Below is a table that shows the estimated time and wage burden for the completion of the CMS-437A and CMS-437B forms by each provider type. See the attached Exhibits A through F for the calculations used to arrive at the figures stated in the table below.

We believe that the CMS-437-A and 437-B for would be completed by a Health Services Manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical or Health Services Manager is \$53.69. (https://www.bls.gov/oes/current/oes119111.htm)

Provider Type	Form Used	Time Required to Complet e Form	# of Providers	Wage Rate	Annual Time Burden	Annual Wage Burden
Inpatient Rehabilitation Facility (IRF) Units	437A	60 min.	846	\$53.69 per hour	846 Hours	\$45,421.74
Inpatient Rehabilitation Facility (IRF) Hospital	437B	60 min.	280	\$53.69 per hour	280 Hours	\$15,033.20
Fringe Benefits and Overhead						\$60,454.94
TOTALS		120 min	1,126		1,126 Hours	\$120,909.88

13. Capital Cost of Burden

There are no capital costs associated with this collection.

14. Federal Cost Estimates

Routine costs associated with this form are incurred by the Federal Government in the normal course of business; therefore, there are no additional costs to the Federal Government.

15. Program/Burden Changes

A. Increased Time Burden

In the previous PRA package, which was submitted in 2016, we had estimated that it would take only **15 minutes** for a medical health services manager at an IRF unit or IRF hospital to complete the CMS-437A or CMS-437B form. However, upon giving serious consideration to this matter, we have determined that this previous burden estimate is extremely low for several reasons. First, the CMS-437A form is 9 pages in length and the CMS-437B for is 7 pages in length. Each of these forms contains multiple sections that must be completed. Second, while each section required only a "Yes", "No" or "N/A" response, the person completing the form may need to speak to others, refer to supporting documents or perform research in order to get the information required to properly respond to each question. Therefore, we believe that a more accurate time burden estimate for the completion of the CMS-437A and CMS-437B forms would be **60 minutes** each.

In the prior PRA package, the annual hourly burden was estimated to be **120 hours** across all IRFs. In this PRA package, we have estimated that the annual hourly burden across all IRFs to complete the CMS-437A and CMS-437B forms to be **1,126 hours**. This is an increase in the annual hourly burden of **1,006 hours**. This increase in the time burden associated with the completion of the CMS-437A and CMS-437B forms is due to several factors. First, we increased the estimated time required to complete the CMS-437A and CMS-437B worksheets from **15 minutes** (as stated in the previous PRA package) to **60 minutes**. Second, there are 648 more IRFs now than there were at the time of the writing of the previous PRA package.

B. Increased Cost Burden

In the previous PRA package, it was estimated that the total cost burden for the completion for the CMS-437A and CMS-437B forms was \$3,781. In this PRA package we have estimated that the total cost burden for the completion of these forms is \$120,909.88. This is an increase in the cost burden of \$117,128.88. This may seem like a large increase in the cost burden associated with the completion of the CMS-437A and CMS-437B forms. However, we believe that the previous cost estimate was not calculated

properly and was way too low for several reason.

First, in the previous PRA package, the total number of IRF units and hospitals was stated to be 478. At this time, there are **846** IRF units and **280** IRF hospitals, which combined adds up to a total number of **1,126** IRFs. The number of IRFs have increased by **648** since the last PRA package was filed. The increased number of IRFs contributes to the increased time and cost burden stated in this PRA package.

Second, as stated above, we have increased the estimated time burden for completion of the CMS-437A and CMS-437B forms to **45 minutes** per form. This increased time burden estimate contributes to the increased time and cost burdens stated in this PRA package.

Finally, it appears that the cost burden estimate in the previous PRA package did not include the cost of fringe benefits and overhead. In this PRA package, we have included in our burden estimate, the cost for fringe benefits and overhead in the amount of \$60,454.94 (100% of the total wages). The inclusion of fringe benefits and overhead also contributes to the increased cost burden stated in this PRA package.

16. Publication and Tabulation Dates

There are no publication and tabulation dates with this collection.

17. Expiration Date

CMS will display the OMB expiration date.