

Supporting Statement for
Rehabilitation Unit & Hospital Criteria Worksheet
CMS-437A and CMS-437B

A. BACKGROUND

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

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

Inpatient Rehabilitation Facilities (IRFs) are free-standing rehabilitation hospitals and rehabilitation units in an acute care hospital provide an intensive rehabilitation program. Patients admitted to an IRF must be able to tolerate at least three hours of intense rehabilitation services per day.

IRF hospitals and units must meet a 60 percent rule imposed by CMS, which requires 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 1286(j) of the Social Security Act effective January 1, 2002.

The CMS regulations at 42 CFR §412.20 through §412.29 provide that 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 at a higher rate under the specialized CMS payment systems known as the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS).

Sections 412.20 to 412.29 describe the criteria under which these specialty hospitals and specialty distinct-part hospital units are excluded from the IPPS. Forms CMS-437A and CMS-437B are used by IRFs to attest to meeting these criteria.

Beginning in 2002, State Survey Agency (SA) surveyors performed IPPS exclusion surveys of IRF units and hospitals and completed the CMS-437A and CMS-437B forms to verify that the exclusion criteria were met by these IRF units and hospitals.

However, beginning on November 5, 2007¹, CMS began allowing the IRF hospitals and units to complete and submit the CMS-437A and CMS-437B forms (as applicable) to the CMS Regional Offices through their respective State Survey Agency annually, as a self-attestation indicating they continued to meet the IPPS exclusion criteria. This self-attestation attestation procedure is defined in the State Operations Manual (SOM) Section 3100 (CMS Pub 100-07).

¹ See S&C 08-03, 11/05/2007

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In 2012, CMS changed the frequency of self-attestation for IRFs from annually to once every three years². Now, IRFs must attest that they meet the requirements for IPPS exempt status prior to initially being placed into excluded status. Additionally, IRFs must re-attest to meeting the exclusion criteria once every three years thereafter.

We have revised the CMS-437A and 437B forms so that they more adequately reflect the regulatory requirements of §412.20 to §412.29. More specifically, we have updated the text in the 3rd column of the form, which tells the facility what actions must be taken and what information must be verified to receive IPPS excluded status. These revisions were made because the instructions to the facility were vague and did not provide enough information to the person completing the form about what they are supposed to do. In some cases the instructions were not in alignment with the CMS regulations.

B. JUSTIFICATION

1. Need and Legal Basis

Certain specialty hospitals and hospital specialty distinct-part units may be excluded from the Medicare Inpatient 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 purpose of the CMS-437A and CMS-437B forms are to allow inpatient rehabilitation facility (IRF) units and hospitals (hereinafter referred to as “IRF units” and “IRF hospitals”) to request an exemption from the Medicare hospital Inpatient Prospective Payment System (IPPS). 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 Inpatient Psychiatric Units (IPFs) are located in §412.27.

2. Information Users

For first time verification requests for exclusion from IPPS, an IRF hospital or IRF unit must

² See S&C 13-04-IRF

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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. Use of Information Technology

The CMS-437A or CMS-437B form 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. Duplication

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

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

6. Less Frequent Collection

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. Special Circumstances

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 was published on August 9, 2022 (87 FR 48482).

On or about September 5, 2022, CMS received a request for extension of the 60-day public comment period from a stakeholder. This request was granted.

The extension notice was published in the Federal Register on October 11, 2022 (87 FR 61333). The extended comment period ended on November 16, 2022. Three public comments were received in reference to the collection instrument. Subsequently, the collection instrument was revised to correct errors in the guidance and verification requirements sections of the forms.

The text of the public comments received and CMS' responses are attached as a separate document.

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.

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11. Sensitive Questions

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

12. Estimate of Burden (Hours and Wages)

The CMS-437A form is completed by inpatient rehabilitation facilities (IRFs) that are ***distinct part units*** of a hospital. The purpose of the CMS-437A form is to allow IRF units to request an exemption from the Medicare hospital Inpatient Prospective Payment System (IPPS). This exemption from the IPPS payment system allows IRF units to receive payment from Medicare at a higher rate through the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS).

The CMS-437A form is completed by new rehabilitation ***units*** when requesting an initial exemption from the IPPS payment system. According to the CMS Survey & Certification Quality, Certification, and Oversight Records System (S&C QCOR System), from 2016 through 2021, there is an average of 1 new inpatient rehabilitation ***unit*** established each year.

The CMS-437A form is also completed by ***existing*** IRF ***units*** every 3 years to maintain their IPPS exempt status. According to the CMS Survey & Certification Quality, Certification, and Oversight Records System (S&C QCOR System), there are currently 1,152 existing inpatient rehabilitation ***units***. Since IRF units only submit the CMS-437A form every 3 years, this would equate to approximately **384** CMS-437A forms being submitted per year.

- 1,152 divided by 3 years = 384 CMS-437A forms submitted per year

The CMS-437B form is completed by inpatient rehabilitation ***hospitals***. The purpose of the CMS-437B form is to allow the inpatient rehabilitation ***hospitals*** to request an exemption from the Medicare Hospital Inpatient Prospective Payment System (IPPS). This exemption allows the inpatient rehabilitation ***hospitals*** to be paid a higher rate by Medicare through the Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS).

According to the S&C QCOR system, between fiscal years 2016 to 2021, there were an average of **12** new inpatient rehabilitation ***hospitals*** established per year (See Table 2 below).

Table 1. Average Number of New Rehabilitation Hospitals Between 2016 - 2021

Fiscal Year	Number of New Inpatient Rehabilitation Hospitals
2016	15
2017	6

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2012	12
2019	13
2020	16
2021	12
6 Year Average	12 (74/6 = 12.33)

The CMS-437B form must also be completed and submitted every 3 years by *existing* IRF *hospitals*, to maintain their IPPS exempt status. According to the CMS QCOR system, there are currently 300 existing IRF hospitals. This would equate to approximately **100** CMS-437B forms submitted per year (300 divided by 3 years = 100).

a. Time and Cost Burden Related to the Completion of CMS-437A forms by *New Inpatient Rehabilitation Facility Units*.

As stated above, there is approximately 1 new IRF unit established each year. We estimate that it would take **1 hour** for a *new* IRF *unit* to complete the CMS-437A form.

We further estimate that the total annual time burden for completion of all CMS-437A forms, *across all new* IRF *units* per year, would be **1 hour**.

- 1 *new* IRF *unit* per year x 1 hour per each CMS-437A form = 1 hour per year

We believe that the person at the *new* IRF *unit* who would complete the CMS-437A form would have a job that falls within the U.S. Bureau of Labor Statistics' job category of "Medical and Health Services Manager. The mean hourly wage for a Medical and Health Services Manager is \$57.12.³ This wage, adjusted for the employer's overhead and fringe benefits, would be \$114.24.

We estimate that the cost burden for completion of the CMS-437A form by *each new* rehabilitation *unit* would be \$114.24:

- 1 hour x \$114.24 per hour = \$114.24

We further estimate that the total cost burden for the completion of all CMS-437A forms *across all new* rehabilitation *units* established per year would be \$114.24.

- 1 hour per year x \$114.24 per hour = \$114.24 per year

b. Time and Cost Burden Related to the Completion of CMS-437A forms By *Existing Inpatient Rehabilitation Facility Units*.

We estimate that the time burden for completion of a CMS-437A form by *each existing* IRF *unit* would be **1 hour**.

³ <https://www.bls.gov/oes/current/oes119111.htm>

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We further estimate that the total annual time burden **across all existing** IRF **units** submitting the CMS-437A forms each year would be **384 hours**.

- 384 **existing** IRF units x 1 hour per each CMS-437A form = 384 hours

We believe that the person at the **existing** IRF **units** who would complete the CMS-437A would be a Medical and Health Services Manager. As stated above, the adjusted hourly wage for a Medical and Health Services Manager is **\$114.24**.

We estimate that the cost burden for the completion of **each** CMS-437A form by **each existing** IRF **unit** would be **\$114.24**.

- 1 hour per year x \$114.24 per hour = \$114.24 per year

We further estimate that the cost burden for the completion of **all** CMS-437A form **across all existing** IRF **units** would be **\$43,868**.

- 384 hours x \$114.24 = \$43,868.16

c. **Time and Cost Burden Related to Completion of the CMS-437B Form by New Inpatient Rehabilitation Hospitals.**

We estimate that it would take approximately 1 hour for **each new** rehabilitation **hospital** to complete the CMS-437B form.

We believe that the person at the IRF **hospital** who would complete the CMS-437B form would have a job that falls under the U.S. Bureau of Labor Statistics job category of “Medical and Health Services Manager. The adjusted hourly wage for the job of Medical and Health Services Manager is **\$114.24**.

We further estimate that the total annual time burden **across all new** IRF **hospitals** per year would be **12 hours**.

- 12 new IRF **hospitals** per year x 1 hour per each CMS-437B form = 12 hours

We estimate that the cost burden to **each new** IRF **hospital** for the completion of a **CMS-437B** form would be **\$114.24**:

- 1 hour x \$114.24 per hour = \$114.24

We further estimate that the total annual cost burden **across all new** IRF **hospitals** for the completion of **all** CMS-437B forms would be **\$1,371**.

- 12 hours x \$114.24 = \$1,370.88

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d. Time and Cost Burden Related to Completion of form CMS-437B by Existing Inpatient Rehabilitation Hospitals.

The estimated time burden for the completion of the CMS-437B form by *each existing* IRF *hospital* is **1 hour**.

We estimate that the total annual time burden *across all existing* IRF *hospitals* for completion of the CMS-437B form would be **100 hours**.

- 100 CMS-437B forms per year x 1 hour per each form = 100 hours

We further estimate that the cost burden for the completion of the *CMS-437B* form by *each existing* IRF *hospital* would be **\$114.24**.

- 1 hour per form x \$114.24 per hour = \$114.24

Finally, we estimate that the total annual cost burden for the completion of the CMS-437B forms, *across all existing* IRF *hospitals* would be **\$11,424**.

- 100 hours x \$114.24 = \$11,424

e. Summary of Time & Cost Burdens for the CMS-437A and CMS-437 forms

Time Burden for Completion Of Each CMS-437A & 437B By Each New IRF Units & Hospitals

Time for completion of <i>each</i> form CMS-437A by <i>each new</i> IRF unit	1 hour
Time for completion of <i>each</i> form CMS-437B by <i>each new</i> IRF hospital	1 hour
TOTAL:	2 hours

Time Burden for Completion Of All CMS-437A & 437B Forms Across All New IRF Units & Hospitals

Time for completion of <i>all</i> form CMS-437A <i>across all new</i> IRF units	1 hour
Time for completion of <i>all</i> form CMS-437B <i>across all new</i> IRF hospitals	12 hours
TOTAL	13 hours

Time Burden for Completion Of All CMS-437A & 437B Forms Across All Existing IRF Units & Hospitals

Time for completion of <i>all</i> form CMS-437A <i>across all existing</i> IRF units	384 hours
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Time for completion of all form CMS-437B across all existing IRF hospitals	100 hours
TOTAL	484 hours

Cost Burden for Completion Of **Each CMS-437 Form By **Each New** IRF Units & Hospitals**

Cost for completion of each form CMS-437A by each new IRF unit	\$114.24
Cost for completion of each form CMS-437B by each new IRF hospital	\$114.24
TOTAL	\$228.48

Cost Burden for Completion Of **All CMS-437A & 437B Forms **Across All New** IRF Units & Hospitals**

Cost for completion of all form CMS-437A across all new IRF units	\$ 114.24
Cost for completion of all form CMS-437B across all new IRF hospitals	\$1,370.88
TOTAL:	\$1,485.12

Cost Burden for Completion Of **All CMS-437A & 437B Forms **Across All Existing** IRF Units & Hospitals**

Cost for completion of all form CMS-437A across all existing IRF units	\$43,868
Cost for completion of all form CMS-437B across all existing IRF hospital	\$11,424
TOTAL:	\$55,292

13. Capital Cost of Burden

There no capital costs are associated with this collection.

14. Federal Cost Estimates

Routine costs are incurred by the Federal Government in the normal course of business in connection with these forms. There are no additional costs to the Federal Government.

15. Program/Burden Changes

The table below shows the change in time and cost burden between the previous PRA package and the current PRA package.

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Tasks	Total Requested	Due to Adjustment in OPDIV/Office Estimate	Currently Approved
a. Annual Responses for CMS-437A	385	-461	846
b. Annual Responses for CMS-437B	112	-168	280
c. Annual time burden for completion of <u>all CMS-437A</u> forms <u>across all new</u> rehab <u>units</u> .	1 hour	+ 1 hour	0 hours
d. Annual time burden for completion of <u>all CMS-437A</u> forms <u>across all existing</u> rehab <u>units</u> .	384 hours	-462 Hours	846 hours
e. Annual time burden for completion of <u>all CMS-437B</u> forms <u>across all new</u> rehab <u>hospitals</u> .	12 hours	+12 hours	0 hours
f. Annual time burden for completion of <u>all CMS-437B</u> forms <u>across all existing</u> rehab <u>hospitals</u> .	100 hours	-180 hours	280 hours
g. Annual cost burden for completion of <u>all CMS-437A</u> forms <u>across all new</u> rehab <u>units</u> .	\$114	+\$114	\$0
h. Annual cost burden for for completion of <u>all CMS-437A</u> forms <u>across all existing</u> rehab <u>units</u> .	\$43,868	-\$46,975	\$90,843
i. Annual cost burden for for completion of <u>all CMS-437B</u> forms <u>across all new</u> rehab <u>hospitals</u> .	\$1,371	+\$1,371	\$0
j. Annual cost burden for burden for completion of <u>all CMS-437B</u> forms <u>across all existing</u> rehab <u>hospitals</u> .	\$11,424	-\$18,642	\$30,066
Total Responses	497 Responses	-629 Responses	1,126 Responses
Total Hour Burden	497 hours	-629 hours	1,126 hours
Total Cost Burden	\$56,777	-\$64,133	\$120,910

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As the above table shows, there has been a significant decrease across all the numbers for this PRA package. For example, the number of responses has decreased by 629. The total annual time burden has decreased by 629 hours and the total annual cost burden has decreased by \$65,618.

We believe that the decreased number of responses and total annual burden hours is due to an overestimate in the number of responses in the previous PRA package. We say this because, in the previous PRA package, it stated that there were 1,126 total responses. However, in 2017, there were only 258 existing and 6 new IRF hospitals. Also, in 2017, there was only 1 new and 1,150 existing IRF units. In addition, as the CMS 437A form is only submitted every 3 years by the existing IRF units, only approximately 383 out of the existing 1,150 IRF units would be submitting the CMS-437A form each year. Therefore, at the time of submission of the previous PRA package, there should have been only about 648 annual respondents. (258 existing IRF hospitals + 6 new IRF hospitals + 1 new IRF unit + 383 existing IRF units submitted annually = 648).

In this PRA package, we updated the mean hourly wage for the Medical & Health Services Manager from \$53.69, as stated in the previous PRA package to the current BLS mean hourly rate of \$57.12 (unadjusted rate). However, this has not caused an increase in the total annual cost burden.

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 on the CMS-437A and CMS-437B forms.