A. BACKGROUND

We request an extension of the OMB approval for a worksheet titled "**Psychiatric Unit Criteria Work Sheet (CMS-437).**" Form CMS-437 is approved as OMB Control number 0938-0358.

Medicare has several types of schedules with which payments are made to inpatient hospitals. Acute care hospitals are paid by Medicare using the Inpatient Prospective Payment System (IPPS). Hospital outpatient services are paid by Medicare using the Medicare Hospital Outpatient Prospective Payment System (HOPPS). Inpatient Psychiatric Facilities and Inpatient Psychiatric Units are paid by Medicare using the Inpatient Psychiatric Facility Prospective Payment System (IPU PPS).

However, in order for inpatient psychiatric hospitals and units to be paid by Medicare under the higher paying Inpatient Psychiatric Facility Prospective Payment System, they must prove that they meet the requirements to be exempt from receiving payment under the lower paying Inpatient Prospective Payment System (IPPS).

Form CMS-437 is used by Inpatient Psychiatric Units (IPUs) to attest to meeting the necessary requirements that make them exempt for receiving payment from Medicare under the Inpatient Prospective Payment System (IPPS). These IPUs must use the CMS-437 form to attest that they meet the requirements for IPPS exempt status prior to being placed into IPPS excluded status. IPUs must re-attest to meeting the IPPS exclusion criteria annually, as required by 42 CFR §412.25.

CMS regulations at 42 CFR §412.20 through §412.29 describe the criteria under which specialty hospitals and specialty distinct-part hospital units are excluded from the Inpatient Prospective Payment System (IPPS).

An Inpatient Psychiatric Facility (IPF) is defined as a facility which:

- Is primarily engaged in providing, by or under the supervision of a Doctor of Medicine or Osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons;
- Satisfies the requirements of §1861(e)(3) through (e)(9) of the Social Security Act (general hospital requirements);
- Maintains clinical and other records on all patients as the Secretary finds necessary
 to determine the degree and intensity of the treatment provided to individuals
 entitled to hospital insurance benefits under Part A; and
- Meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals receiving services in the institution.

In the past, SA surveyors would conduct onsite IPPS exclusion surveys to verify that the IPPS exclusion criteria were met by the facility. The SA surveyor would complete the CMS-437 form prior to placing an IPU into IPPS excluded status.

However, on November 5, 2007, CMS suspended the requirement for onsite IPPS exclusion surveys and instead began allowing IPU units to self-attest to meeting the IPPS exclusion criteria. (See: Survey &Certification Memo 08-03, dated 11/05/2007). As a result, instead of having the SA perform an IPPS exclusion surveys, the IPUs are now required to complete the CMS-437 form annually as a self- attestation indicating they continued to meet the IPPS exclusion criteria.

IPUs complete and submit their 437 form to the CMS Regional Offices through the SA. The IPPS exclusion attestation procedures are defined in the State Operations Manual (SOM) at Section 3100 (CMS Pub 100-07) and the FY2017 Mission Priority Document (MPD), The State Operations Manual is publically available on the CMS website at: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=ascending

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) units, Inpatient Rehabilitation Facilities (IRFs) hospitals and Inpatient Psychiatric Facilities (IPFs) and Inpatient Psychiatric Units (IPUs).

The exclusion of these specialty hospitals and distinct-part specialty units of hospitals is optional on the part of the provider. However, exclusion from the IPPS permits the specialty hospitals and distinct-part specialty units of hospitals to be paid at a different payment rate to reflect the cost of providing specialized services.

Inpatient Psychiatric Units (IPUs) units within a hospital 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. Excluded IPU units within a hospital are paid under the Inpatient Psychiatric Facility Prospective Payment System (IPU PPS) as specified by Section 124 of the Medicare, Medicaid, and State Children's Health Insurance Program (SCHIP) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), which amended Section 1886(s) 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). Exclusion criteria that are specific to IPUs are located in §412.27.

2. Information Users

For verification requests for exclusion from IPPS, an IPU unit must notify the Regional Office (RO), servicing the State in which it is located, that it intends to seek excluded status from the IPPS. This information is submitted to the State Agency no later than 5 months before the date the hospital/unit would become subject to IPU-PPS.

IPUs already excluded from IPPS will be provided a copy of the 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 CMS-437 to the CMS RO through the SA.

The SA must transmit the worksheets to the RO at least 60 days prior to the end of the IPU's cost reporting period. This information will be reviewed by the CMS RO when determining exclusion from the IPPS. IPU units that have already been excluded need not reapply for exclusion.

IPUs must complete and submit the CMS-437 form to the SA on an annual basis. The IPPS exempt status of the IPU will be reevaluated by the RO every year to determine whether they continue to meet the exclusion criteria.

SA surveyors will periodically conduct onsite verification of the IPPS exclusion criteria of IPUs. Verification of the IPPS exclusion status of an IPU is performed when the SA is onsite conducting a complaint survey. Also, the SA performs IPPS exempt status validation surveys on a random 5% sample of the IPU population annually. These IPPS exempt status validation surveys are performed to ensure that the selected IPUs meet the criteria for exclusion from the IPPS payment system.

3. Use of Information Technology

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

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 for an IPU to obtain an exclusion from the Medicare IPPS. 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. Less Frequent Collection

An IPU must attest to meeting all requirements for the IPPS exclusion prior to being placed in excluded status. The re-verification process is completed annually for IPUs 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 published on March 19, 2021 (86 FR 14926). There were no public comments received.

The 30-day Federal Register notice published June 1, 2021 (86 FR 29264).

9. Payment/Gifts to Respondent

There are no payments or gifts involved in this information collection. An IPU must complete the CMS-437 form in order to attest that they meet the requirements for IPPS exempt status so that they can be exempted from payment under the CMS Inpatient Prospective Payment System (IPPS) payment system and instead receive payment under the under the Inpatient Psychiatric Facility Prospective Payment System (IPU PPS).

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)

Over the past 5 years the number of psychiatric units in hospitals has decreased. Below is a table that shows the number of psychiatric units from CY 2016 to CY 2020. This table also shows that the average number of psychiatric units between calendar years 2016 to 2020 is 1,598. For the purposes of this burden calculation we will use the average number of psychiatric units between 2016 and 2020 instead of the current number of psychiatric units in the U.S. because this number would provide the best picture of the number of psychiatric units over time.

<u>Years</u>	<u>Number of Psychiatric</u> <u>Units in U.S</u>
CY 2016	1,627
CY 2017	1613
CY 2018	1,603
CY 2019	1,586
CY 2020	1,561
TOTAL	7,990
Average Number of Psychiatric Units between 2016 and 2020 (7,990 /5 = 1,598)	1,598

a. Time and Cost Burden for Completion of the CMS-437 Form.

Psychiatric units are required to complete the CMS-437 form and submit the completed form to the State Survey Agency annually. We estimate that it will take approximately 45 minutes for the psychiatric unit staff to complete the CMS-437 form.

There are an average of 1,598 psychiatric units in the U.S. We estimate that the time burden *across all* of these psychiatric units for the completion of the CMS-437 would be **1,199 hours.**

- 45 minutes x 1,598 psych units = 71,910 minutes
- 71,910 minutes divided by 60 minutes per hour = 1,198.5 hours

We believe that the person who would complete the CMS-437 form would be an employee such as a Nurse Manager or Director of Nursing or facility business manager. We believe that this person's job duties would fall under the U.S. Bureau of Labor Statistic's job category of "Health and Medical Services Manager." According the U.S. Bureau of Labor Statistics, the mean hourly wage for this job is \$55.37. (https://www.bls.gov/oes/current/oes119111.htm). This wage, adjusted for the employer's overhead and fringe benefits, would be \$110.74.

We estimate that the cost burden for the completion of the CMS-437 form by *each* psychiatric unit would be **\$83.07**.

- \$110.74 divided by 60 minutes = \$1.846 per minute
- \$1.846 per minute x 45 minutes = \$83.07

OR

- \$110.74 divided by 4 = \$27.69 per 15 minutes
- $$27.68 \times 3 = $83.07 \text{ (per 45 minutes)}$

We further estimate that the total cost burden *across all* psychiatric units in the U.S. would be **\$132,777.26.**

• \$110.74 per hour x 1,199 hours = \$132,777.26

b. <u>Time and Cost Burden Associated with Copying, Filing and Mailing the Completed CMS-437 Form to the State Survey Agency.</u>

After completing the CMS-437 form, we believe that the Medical or Health Services Manager would give the completed form to a medical secretary to perform the following tasks:

- 1. Photocopy the original signed copy;
- 2. Prepare a cover letter to send to the SA with the completed CMS-437 form;
- 3. File the copy of the CMS-437 form and copy of the cover letter in the appropriate facility file;
- 4. Prepare a mailing envelope in which to mail the completed CMS-437 form and cover letter;
- 5. Place the original copy of the completed CMS-437 form and cover letter into the prepared envelope and sealing the envelope;
- 6. Affix the proper amount of postage to the envelope;
- 7. Place the envelope into a mailbox or into an outgoing mail bin for mailing.

We estimate that it would take approximately **20 minutes** for the Medical Secretary to complete the above-stated tasks when processing *each* psych units' annual CMS-437 form submission.

We further estimate that the total annual time burden *across all* 1,598 psychiatric units for the performance of these tasks would be **533 hours.**

- 20 minutes x 1,598 psych units = 31,960 minutes
- 31,960 minutes divided by 60 min. per hour = 532.66 hours

According to the U.S. Bureau of Labor Statistics, the average hourly wage for a Medical Secretary is \$17.83. (See: https://www.bls.gov/oes/2018/may/oes436013.htm) This wage adjusted for the employers overhead and fringe benefits would be \$35.66.

We estimate that the cost burden associated with the performance of the above-stated tasks by the medical secretary per *each* CMS-437 form completed would be **\$11.88**.

- \$35.66 divided by 60 minutes = \$0.594 per minute
- \$0.594 per minute x 20 minutes = \$11.88 (per 20 minutes)

We further estimate that the total annual cost burden *across all* psychiatric units for the performance of the above-stated tasks by the medical secretary would be **\$19,006.78**.

• \$35.66 per hour x 533 hours = \$19,006.78

c. Summary of Time and Cost Burden Associated with Completion of the CMS-437 form.

Time Burden for Completion of EACH CMS-437 form

TOTAL	65 minutes
Processing tasks performed by Medical Secretary	20 minutes
Completion of the CMS-437 form	45 minutes

Time Burden for Completion of ALL CMS-437 form

TOTAL	1.732 hours
Processing tasks performed by Medical Secretary	533 hours
Completion of the CMS-437 form	1,199 hours

Cost Burden for Completion of EACH CMS-437 form

Completion of the CMS-437 form	\$83.07
Processing tasks performed by Medical Secretary	\$11.88
TOTAL	\$94.95

Cost Burden for Completion of ALL CMS-437 form

TOTAL	\$151,784.04
Processing tasks performed by Medical Secretary	\$ 19,006.78
Completion of the CMS-437 form	\$132,777.26

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

The table below shows the changes in burden since the last PRA package submission.

	Total Requested	Due to Adjustment in OPDIV/Office Estimate	Currently Approved
a. Annual Responses for CMS-437	1,598	-18	1,616
b. Annual time burden to complete <u>each</u> CMS-437 form	1.083 hours	+0.33 hour	0.75 hour
c. Annual time burden <u>across all</u> CMS-437 forms	1,732 hours	+ 520 hours	1,212 hours
d. Annual cost burden per <u>each</u> CMC-437 form	\$94.95	Unable to determine	Not stated
e. Annual Cost Burden <u>across all</u> CMS-437 forms	\$151,784	+ \$39,286	\$112,498

As the above table states, the total annual burden hours have increase by 520 hours and the total annual cost burden has increased by \$39,286. This increase is due to two factors.

First we updated the burden calculations to include the time and cost burden required for a medical secretary to process the CMS-437 form after it has been completed. See section 12(b) for a list of the tasks that would be performed by the medical secretary. This time and cost burden was not included in the previous PRA package, but is a necessary part of the completion of the CMS-437.

Second, we updated the job category for the person that would complete the CMS-437 form from a Medical Administrator at an hourly wage rate of \$46.41 to the job category of Medical and Health Services Manager which has a mean hourly wage of \$55.37. We also doubled this wage rate to account for the employer's overhead and fringe benefits. This is a required practice.

16. Publication and Tabulation Dates

There are no publication and tabulation dates with this collection.

17. Expiration Date

CMS will display the expiration date on the CMS-437 form on the lower left hand corner of each page of the CMS-437 form.

18. <u>Certification Statement</u>

There are no exceptions to the certification statement.

C. <u>COLLECTION OF INFORMATION EMPLOYING STATISTICAL METHODS</u>

There are no statistical methods associated with this collection.