

basic tenets were carried forward and broadened by the formation of the Communicable Disease Center (CDC) in 1946. CDC was conceived of as a well-equipped, broadly staffed agency used to translate facts about analysis of morbidity and mortality statistics on communicable diseases and through field investigations.

It was soon recognized that control measures (such as the DDT spraying for malaria) did not alleviate the threat of disease reintroduction. In 1950, the Malaria Surveillance Program began, and in 1952, the National Surveillance

Program started. Both programs were based on the premise that diseases cannot be diagnosed, prevented, or controlled until existing knowledge is expanded and new ideas developed and implemented. The original scope of the National Surveillance Program included the study of malaria, murine typhus, smallpox, psittacosis, diphtheria, leprosy, and sylvatic plague. Over the years, the mandate of CDC has broadened in preventive health activities and the surveillance systems maintained have expanded. This

program is authorized under the Public Health Service Act, Section 301 and 306 (42 U.S.C. 241 and 242K).

This ICR covers surveillance activities for these four, rare diseases:

1. Creutzfeldt-Jakob Disease (CJD)
2. Reye Syndrome
3. Kawasaki syndrome
4. Acute Flaccid Myelitis

Annual burden is estimated to decrease by 23 hours to 167 total hours since the last approval. There is no cost to respondents other than the time to participate.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Epidemiologists .....	CJD .....	10	2	20/60
	Kawasaki Syndrome .....	25	10	15/60
	Reye Syndrome .....	50	1	20/60
	Acute Flaccid Myelitis .....	100	4	12/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10520, CMS-437A and CMS-437B]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of

information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by July 26, 2019.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 OR, Email: *OIRA\_submission@omb.eop.gov*.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' website address at website address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>.

1. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

2. Call the Reports Clearance Office at (410) 786-1326.

**FOR FURTHER INFORMATION CONTACT:** William Parham at (410) 786-4669.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement of a previously approved information collection; *Title of Information Collection:* Marketplace Quality Standards; *Use:* The Patient Protection and Affordable Care Act establishes requirements to support the delivery of quality health care coverage for health insurance issuers offering Qualified Health Plans (QHPs) in

Exchanges. Section 1311(c)(3) of the Patient Protection and Affordable Care Act directs the Secretary to develop a system to rate QHPs on the basis of quality and price and requires Exchanges to display this quality rating information on their respective websites. Section 1311(c)(4) of the Patient Protection and Affordable Care Act requires the Secretary to develop an enrollee satisfaction survey system to assess enrollee experience with each QHP (with more than 500 enrollees in the previous year) offered through an Exchange. Section 1311(h) requires QHPs to contract with certain hospitals that meet specific patient safety and health care quality standards.

This collection of information is necessary to provide adequate and timely health care quality information for consumers, regulators, and Exchanges as well as to collect information to appropriately monitor and provide a process for a survey vendor to appeal HHS' decision to not approve a QHP Enrollee Survey vendor application. *Form Number:* CMS-10520 (OMB control number: 0938-1249); *Frequency:* Annually; *Affected Public:* Public sector (Individuals and Households), Private sector (Business or other for-profits and Not-for-profit institutions); *Number of Respondents:* 264. *Total Annual Responses:* 264; *Total Annual Hours:* 348,764. For policy questions regarding this collection contact Nidhi Singh Shah at 301-492-5110. *Type of Information Collection Request:* Revision of a currently approved collection.

2. *Title of Information Collection:* State Agency Sheets for Verifying Exclusions from the Inpatient Prospective Payment System and Supporting Regulations—Rehabilitation Unit/Rehabilitation Hospital Criteria Worksheets; *Use:* The purpose of this information collection is to renew forms CMS-437A and 437B. Inpatient Rehabilitation Facility (IRF) hospitals and units must initially attest that they meet the Inpatient Prospective Payment System (IPPS) exclusion criteria set forth at 42 CFR 412.20 to 412.29 prior to being placed into IPPS exempt status. Form CMS-437A must be completed by IRF units and form CMS-437B must be completed by IRF hospitals.

For first time verification requests for exclusion from the IPPS, an IRF unit or hospital must notify the Regional Office (RO) servicing the State in which it is located that it believes it meets the criteria for exclusion from the IPPS. Currently, all new IRF units or hospitals must provide written certification that the inpatient population it intends to serve will meet the requirements of the

IPPS exclusion criteria for IRFs. The completed CMS-437A and 437B forms are submitted to the State Agency (SA) no later than 5 months before the date the IRF unit or hospital would become subject to Inpatient Rehabilitation Facility Prospective Payment System (IRF-PPS). For IRF units and hospitals already excluded from the IPPS, annual onsite re-verification surveys by the SA are no longer required. IRF units and hospitals must now re-attest to meeting the exclusion criteria every 3 years thereafter.

IRF units and hospitals that have already been excluded need not reapply for exclusion. These facilities will automatically be reevaluated yearly to determine whether they continue to meet the exclusion criteria. For the tri-annual re-verification, IRF units and hospitals will be provided with a copy of the appropriate CMS-437 worksheet at least 5-months prior to the beginning of its cost reporting period, so that the IRF unit or hospital official may complete and sign an attestation statement and complete and return the appropriate form CMS-437A or CMS-437B at least 5-months prior to the beginning of the cost reporting period. However, Fiscal Intermediaries (FIs) will continue to verify, on an annual basis, compliance with the 60 percent rule (42 CFR 412.29(b)(2)) for IRF units and hospitals through a sample of medical records and the SA will verify the medical director requirement.

The SA will notify the RO at least 60 days prior to the end of the IRF unit's or hospital's cost reporting period of the status of compliance or non-compliance with the payment requirements. The information collected on the 437A and 437B forms, along with other information submitted by the IRF is necessary for determining the IRF's IPPS exclusion status. *Form Number:* CMS-437A and CMS-437B (OMB control number: 0938-0986); *Frequency:* tri-annually; *Affected Public:* Private sector (Business or other for-profits); *Number of Respondents:* 1,126; *Total Annual Responses:* 1,126; *Total Annual Hours:* 1,126. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

Dated: June 21, 2019.

**William N. Parham, III,**

*Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-153, CMS-R-235, CMS-10439, CMS-10594, CMS-10328 and CMS-460]

#### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Centers for Medicare & Medicaid Services, HHS.

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments must be received by August 26, 2019.

**ADDRESSES:** When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number \_\_\_\_\_, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.