



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-185, CMS-437 and CMS-10515]

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

AGENCY: Centers for Medicare & Medicaid Services.

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 **[Insert date 30 days after the date of publication in the Federal Register]**.

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

E-mail: 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' Web Site address at Web Site address at <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html>
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. 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: Extension of currently approved collection;
Title of Information Collection: Granting and Withdrawal of Deeming Authority to Private Nonprofit Accreditation Organizations and CLIA Exemption Under State Laboratory Programs;
Use: The information required is necessary to determine whether a private accreditation organization/State licensure program standards and accreditation /licensure process is at least equal to or more stringent than those of the Clinical Laboratory Improvement Amendments of 1988 (CLIA). If an accreditation organization is approved, the laboratories that it accredits are “deemed” to meet the CLIA requirements based on this accreditation. Similarly, if a State licensure program is determined to have requirements that are equal to or more stringent than those of CLIA, its laboratories are considered to be exempt from CLIA certification and requirements. The information collected will be used by HHS to: determine comparability/equivalency of the accreditation organization standards and policies or State licensure program standards and policies to those of the CLIA program; to ensure the continued comparability/equivalency of the standards; and to fulfill certain statutory reporting requirements. Form Number: CMS-R-185 (OMB control number: 0938-0686); Frequency:

Occasionally; Affected Public: Private Sector - Business or other for-profits and Not-for-profit institutions; Number of Respondents: 9; Total Annual Responses: 9; Total Annual Hours: 5,464. (For policy questions regarding this collection contact Arlene Lopez at 410-786-6782.)

2. Type of Information Collection Request: Reinstatement with Change of a previously approved collection; Title of Information Collection: Psychiatric Unit Criteria Work Sheet; Use: 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).

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. Form CMS-437 is used by Inpatient Psychiatric Facilities (IPFs) to attest to meeting the necessary requirements that make them exempt for receiving payment from Medicare under the IPPS. These IPFs must use CMS-437 to attest that they meet the requirements for IPPS exempt status prior to being placed into excluded status. The IPFs must re-attest to meeting the exclusion criteria annually. Form Number: CMS-437 (OMB control number: 0938-0358); Frequency: Annually; Affected Public: Private sector - Business or other for-profits; Number of Respondents: 1,616; Total Annual Responses: 1,616; Total Annual Hours: 1,212. (For policy questions regarding this collection contact Caroline Gallaher at 410-786-8705.)

3. Type of Information Collection Request: Extension of a currently approved collection;

Title of Information Collection: Payment Collections Operations Contingency Plan; Use: Under sections 1401, 1411, and 1412 of the Affordable Care Act and 45 CFR part 155 subpart D, an Exchange makes an advance determination of tax credit eligibility for individuals who enroll in QHP coverage through the Exchange and seek financial assistance. Using information available at the time of enrollment, the Exchange determines whether the individual meets the income and other requirements for advance payments and the amount of the advance payments that can be used to pay premiums. Advance payments are made periodically under section 1412 of the Affordable Care Act to the issuer of the QHP in which the individual enrolls. Section 1402 of the Affordable Care Act provides for the reduction of cost sharing for certain individuals enrolled in a QHP through an Exchange, and section 1412 of the Affordable Care Act provides for the advance payment of these reductions to issuers. The statute directs issuers to reduce cost sharing for essential health benefits for individuals with household incomes between 100 and 400 percent of the Federal poverty level (FPL) who are enrolled in a silver level QHP through an individual market Exchange and are eligible for advance payments of the premium tax credit. The data collection will be used by HHS to make payments or collect charges from issuers under the following programs: advance payments of the premium tax credit, advanced cost-sharing reductions, and Marketplace user fees. The template will be used to make payments in January 2014 and for a number of months thereafter, as may be required based on HHS's operational progress. Form Number: CMS-10515 (OMB control number: 0938-1217); Frequency: Monthly; Affected Public: Private sector (Business or other for-profits and not-for-profit institutions); Number of Respondents: 575; Total Annual Responses: 7,475; Total Annual Hours: 51,175.

(For policy questions regarding this collection contact Jaya Ghildiyal at 301-492-5149).

Dated: November 21, 2017 _____

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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