

STUDY ELIGIBILITY CRITERIA BASED ON POPULATION, INTERVENTION, COMPARATOR, OUTCOME (PICO), AND OTHER ELEMENTS—Continued

Element	Inclusion criteria	Exclusion criteria
Timing .....	<ul style="list-style-type: none"> <li>• Minimum duration of intervention: 2 weeks.</li> <li>• In cross-over studies, any change in outcome measure must exclude data from the first week after end of any prior treatments. This may be accomplished by a washout period of at least 1 week.</li> </ul>	None.
Setting .....	<ul style="list-style-type: none"> <li>• General population.</li> <li>• English language.</li> <li>• Published in peer-reviewed journals.</li> </ul>	<ul style="list-style-type: none"> <li>• Hospital or other acute care settings.</li> <li>• Non-English language text.</li> <li>• Conference abstracts and other non-peer-reviewed data.</li> </ul>

Dated: March 18, 2024.  
**Marquita Cullom,**  
*Associate Director.*  
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**BILLING CODE 4160-90-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

[Document Identifiers: CMS-R-38 and CMS-10400]

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

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 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 May 28, 2024.

**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.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

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

**SUPPLEMENTARY INFORMATION:**

**Contents**

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

- CMS-R-38 Conditions for Certification for Rural Health Clinics and Conditions for Coverage for Federally Qualified Health Centers in 42 CFR 491
- CMS-10400 Establishment of Qualified Health Plans and American Health Benefit Exchanges

Under the 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 requires federal agencies to publish a 60-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.

**Information Collection**

1. *Type of Information Collection Request:* Reinstatement of a previously approved collection; *Title of Information Collection:* Conditions for Certification for Rural Health Clinics and Conditions for Coverage for Federally Qualified Health Centers in 42 CFR 491; *Use:* The Conditions for Medicare Certification (CfCs) for Rural Health Clinics (RHCs) are based on criteria prescribed in law and designed to ensure that each RHC has properly trained staff to provide appropriate care and to assure a safe physical environment for patients. The information collection requirements described herein are needed to implement the Medicare and Medicaid CfCs for a total of 5,349 RHCs. These requirements are similar in intent to standards developed by industry organizations such as the Joint Commission on Accreditation of Hospitals, and the National League of Nursing/American Public Association, and merely reflect accepted standards of management and care to which rural health clinics must adhere.

Federally Qualified Health Centers (FQHCs) are also subject to Conditions for Certification to participate in the Medicare and Medicaid programs. These health and safety standards are the foundation for improving quality and protecting the health and safety of Medicare and Medicaid beneficiaries. The information collection requirements described herein affect approximately 11,252 FQHCs. The current information collection requirements at 42 CFR 491.9(b) and 491.11 are applicable to both RHCs and FQHCs. *Form Number:* CMS–R–38 (OMB control number: 0938–0334); *Frequency:* Recordkeeping and Reporting—Annually; *Affected Public:* Business or other for-profits; *Number of Respondents:* 17,663; *Total Annual Responses:* 17,663; *Total Annual Hours:* 104,245. (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445.)

**2. Type of Information Collection Request:** Revision of a currently approved collection; **Title of Information Collection:** Establishment of Qualified Health Plans and American Health Benefit Exchanges; **Use:** On March 23, 2010, the Patient Protection and Affordable Care Act (PPACA; Pub. L. 111–148) was signed into law, and on March 30, 2010, the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) was signed into law. The two laws implement various health insurance policies. Section 1303 of the PPACA, as implemented in 45 CFR 156.280, specifies standards for issuers of qualified health plans (QHPs) through the Exchanges that cover abortion services for which public funding is prohibited (also referred to as non-Hyde abortion services or non-excepted abortion services). In the Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (2012 Exchange Establishment Rule) (77 FR 18310), we codified the statutory provisions of section 1303 of the PPACA in regulation at 45 CFR 156.280. Under 45 CFR 156.280(e)(5)(ii), each QHP issuer that offers coverage of abortion services for which public funding is prohibited must submit to the State Insurance Commissioner a segregation plan describing how the QHP issuer establishes and maintains separate allocation accounts for any QHP covering abortion services for which public funding is prohibited, and pursuant to § 156.280(e)(5)(iii), each QHP issuer must annually attest to compliance with PPACA section 1303 and applicable regulations. This

segregation plan is used to verify that the QHP issuer's financial and other systems fully conform to the segregation requirements required by the PPACA.

The Centers for Medicare and Medicaid Services (CMS) is renewing this information collection request (ICR) in connection with the segregation plan requirement under 45 CFR 156.280(e)(5)(ii). The burden estimates for this collection of information renewal reflect the time and effort for QHP issuers to submit a segregation plan that demonstrates how the QHP issuer segregates QHP funds in accordance with applicable provisions of generally accepted accounting requirements, circulars on funds management of the Office of Management and Budget (OMB) and guidance on accounting of the Government Accountability Office. CMS is also renewing the ICR in connection with the annual attestation requirement under 45 CFR 156.280(e)(5)(iii). The burden estimate for this ICR reflects the time and effort associated with QHP issuers submitting an annual attestation to the State Insurance Commissioner attesting to compliance with section 1303 of the PPACA. *Form Number:* CMS–10400 (OMB control number: 0938–1156); *Frequency:* Annually; *Affected Public:* Private Sector (business or other for-profits, not-for-profits institutions); *Number of Respondents:* 1,617; *Number of Responses:* 1,617; *Total Annual Hours:* 5,508.75. (For questions regarding this collection, contact Agata Pelka at 667–290–9979).

**William N. Parham, III,**

*Director, Division of Information Collections and Regulatory Impacts, 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–10593]

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

**AGENCY:** Centers for Medicare & Medicaid Services, Health and Human 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 April 29, 2024.

**ADDRESSES:** Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to [www.reginfo.gov/public/do/PRAMain](http://www.reginfo.gov/public/do/PRAMain). Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

**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