Model participants will be required to comply with all applicable data privacy and security laws, including relevant provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy, Security, and Breach Notification Rules (45 CFR parts 160 and 164, subparts A through E) (HIPAA Rules). By performing prior authorization functions on behalf of the Medicare FFS health plan that involve protected health information (PHI), the model participants will be serving as business associates (see 45 CFR 160.103). A business associate relationship will be established between CMS's Medicare FFS health plan and the model participants which will be documented through valid business associate agreements (BAA) that comply with the requirements of the HIPAA Privacy Rule (see 45 CFR 164.502(e) and 164.504(e)). Currently, MACs also function as business associates to CMS's Medicare FFS health plan. CMS will develop the WISeR model's data sharing policies in compliance with the HIPAA Rules and all relevant HIPAA guidance applicable to the use and disclosure of PHI, as well as CMS's overarching privacy and security framework, and other applicable federal laws and regulations.

Additional information is available on the WISeR website at *https://www.cms.gov/priorities/innovation/innovation-models/wiser.*

III. Collection of Information Requirements

Section 1115A(d)(3) of the Act, as added by section 3021 of the Affordable Care Act, states that chapter 35 of title 44, United States Code (the Paperwork Reduction Act of 1995), shall not apply to the testing and evaluation of models or expansion of such models under this section. Consequently, this document need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Dr. Mehmet Oz, having reviewed and approved this document, authorizes Chyana Woodyard who is the **Federal Register** Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Chyana Woodyard,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2025–12195 Filed 6–27–25; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10433]

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 September 2, 2025.

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–10433—Initial Plan Data Collection to Support QHP Certification and other Financial Management and Exchange Operations

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 Collections

1. *Type of Information Collection:* Revision of a currently approved collection; *Title of Information Collection Request:* Initial Plan Data Collection to Support QHP Certification and other Financial Management and Exchange Operations; *Use:* As directed by the rule Establishment of Exchanges and Qualified Health Plans; Exchange Standards for Employers (77 FR 18310) (Exchange rule), each Exchange is responsible for the certification and offering of Qualified Health Plans (QHPs). To offer insurance through an certification standards, such as network adequacy, inclusion of Essential Community Providers (ECPs), and non-

discrimination. The Exchange is responsible for ensuring that QHPs meet these minimum certification standards as described in the Exchange rule under 45 CFR 155 and 156, based on the Patient Protection and Affordable Care Act (PPACA), as well as other standards determined by the Exchange. Issuers can offer individual and small group market plans outside of the Exchanges that are not QHPs.

Issuers can offer individual and small group market plans outside of the Exchanges that are not QHPs. Such plans are referred to in this document as ''non-Exchange.'' For the risk adjustment program, administrative information is used to identify all non-grandfathered small group and individual market non-Exchange plan offerings eligible for the program. Risk adjustment also requires select data such as rating area, rating factors, and actuarial value (AV) level, to perform calculation of payments and charges.

This information collection request serves as a formal request for the revision of the data collection clearance. We intend to use the instruments in this information collection for the 2025 certification process and beyond, and believe that providing these instruments now will give issuers and other stakeholders more opportunity to familiarize themselves with the instruments before releasing the 2025 application. While we intend to use these instruments in 2025, we may propose further revisions to this data collection in the future as necessary which will include seeking comments through the full 60-day and 30-day public comment periods. *Form Number:* CMS–10433 (OMB control number: 0938–1187); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; State, Local, or Tribal Governments; *Number of Respondents:* 1,073; *Number of Responses:* 1,073; *Total Annual Hours:* 61,154. (For questions regarding this collection, contact Alexandra Gribbin at (667) 290–9977).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2025–12281 Filed 6–30–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx–New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 31, 2025.

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.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Process Data for Organ Procurement and Transplantation Network, OMB No. 0906–xxxx–New.

Abstract: Section 372 of the Public Health Service Act requires that the Secretary of HHS, by awards, provide for the establishment and operation of the Organ Procurement and Transplantation Network (OPTN), which, under oversight of the Health Resources and Services Administration (HRSA), operates the U.S. organ procurement and transplantation system. The Secretary/HRSA may direct the collection of data in accordance with the regulatory authority in 42 CFR 121.11 of the OPTN Final Rule. HRSA, in alignment with the Paperwork Reduction Act of 1995, submits data elements for collection to OMB for official federal approval.

A 60-day Notice was published in the **Federal Register**, 89 FR 87592 (November 4, 2024). The 60-day **Federal Register** Notice publication generated 53 public comments, with the majority submitted by transplant centers. The public comments offered input to improve the quality and clarity of the data forms, including by standardizing the definitions of the terminology used on the forms and making additions and revisions to response options and categories. The respondents also provided feedback on the perceived burden of data collection. They suggested submitting these data on a quarterly, semi-annual, or annual basis, rather than in real-time, to reduce the time and staffing required to report the data to HRSA. Nearly all respondents who commented on the use of automated collection techniques supported efforts to automate data collection in these forms, including coordinating updates with Electronic Health Record vendors and other software developers. Others recommended a phased-in approach with a pilot testing period.

HRSA conducted a thorough review of all the feedback provided by the public during the 60-day publication period. HRSA will incorporate many public comments into the new forms, including through the removal and/or revision of current fields (for example, removing HIV status and Primary Insurance from the Ventilated Patient Form) and explore options to automate the data collection process and incorporate education and training for data respondents to reduce burden and ensure data quality and accuracy. Other suggestions may be further reviewed for consideration in future OMB packages or non-substantive change memos.

Need and Proposed Use of the Information: HRSA and the OPTN Board of Directors use data to develop transplant, procurement, and allocation policies; to determine whether institutional members are complying with policy; to determine member-specific performance; to ensure patient safety; and to fulfill the requirements of the OPTN Final Rule. The regulatory authority in 42 CFR 121.11 of the OPTN Final Rule allows the Secretary of HHS to prescribe data collection. This regulatory authority requires the OPTN data to be made available, consistent with applicable laws, for use by OPTN members, the Scientific Registry of