Wage Index Occupational Mix Survey; Use: Section 304(c) of Public Law 106-554 amended section 1886(d)(3)(E) of the Social Security Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

CMS takes the data collected from the approximately 3,200 IPPS providers participating in the Medicare program and runs the data through mathematical formulas to create the occupational mix adjustment to the wage index. CMS informs hospitals of the occupational mix adjusted wage indexes through notice and comment rulemaking each year. Form Number: CMS-10079 (OMB control number: 0938-0907); Frequency: Annually; Affected Public: Private Sector, Business or other for-profit and not-for-profit institutions; Number of Respondents: 3,100; Number of Responses: 3,100; Total Annual Hours: 1,488,000. (For policy questions regarding this collection contact Noel Manlove at 410-786-5161.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title of *Information Collection:* Recognition of Pass-Through Payment for Additional (New) Categories of Devices under the Outpatient Prospective Payment System and Supporting Regulations; Use: The transitional pass-through provision provides a way for ensuring appropriate payment for new technologies whose use and costs are not adequately represented in the base year claims data on which the outpatient PPS is constructed as required by law. Categories of medical devices will receive transitional pass-through payments for 2 to 3 years from the date payments are initiated for the category. However, the underlying provision is permanent and provides an on-going mechanism for reflecting timely introduction of new items into the payment structure.

Interested parties such as hospitals, device manufacturers, pharmaceutical companies, and physicians apply for transitional pass-through payment for certain items used with services covered in the outpatient PPS. After we receive all requested information, we evaluate the information to determine if the creation of an additional category of medical devices for transitional passthrough payments is justified. We may request additional information related to the proposed new device category, as needed. We advise the applicant of our decision, and update the outpatient PPS during its next scheduled quarterly payment update cycle to reflect any newly approved device categories. We list below the information that we require from all applicants. The following information is required to process requests for additional categories of medical devices for transitional pass-through payments. Form Number: CMS-10052 (OMB control number: 0938–0857); Frequency: Annually; Affected Public: Private Sector, Business or other for-profits; Number of Respondents: 16; Number of Responses: 16; Total Annual Hours: 16. (For questions regarding this collection contact Amanda Rhee at 410-786-3888.)

William N. Parham, III,

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

[FR Doc. 2025–15981 Filed 8–20–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10320, CMS-10561, and CMS-10916]

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 September 22, 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.

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 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 a currently approved collection; Title of Information Collection: Health Care Reform Insurance Web Portal Requirements 45 CFR part 159; Use: In accordance with sections 1103 and 10102 of The Patient Protection and Affordability Care Act, Public Law 111-148 (2010) (Affordable Care Act) the U.S. Department of Health and Human Services (HHS) is tasked with developing and implementing an internet website portal to assist consumers with identifying affordable and comprehensive health insurance coverage options that are available in their State. Consistent with minimizing burden and providing consistency in data collection, the Centers for Medicare & Medicaid Services (CMS) updates its HealthCare.gov collection requirements as regulatory developments occur. There have been no developments since the last approved collection that require changes to the Paperwork Reduction Act (PRA) package. Therefore, we are submitting this request as an extension of the currently approved information collection. Form Number: CMS-10320 (OMB control number 0938-1086); Frequency: Occasionally; Affected Public: State, Local, and Tribal Governments; Number of Respondents: 814; Number of Responses: 814; Total Annual Hours: 50,653. (For questions regarding this collection contact Kimberlee Heckstall at 410-786-1647.)

2. Type of Information Collection Request: Reinstatement without change of a previously approved information collection; Title of Information Collection: Supporting Statement for Essential Community Provider Data Collection to Support QHP Certification; Use: Standards for Essential Community Provider (ECP) requirements are codified at 45 CFR 156.235. Issuers must contract with a certain percentage, as determined by Health and Human Services (HHS), of the available ECPs in the plan's service area. HHS will continue to collect more complete data from such providers so that all issuers are held to a more uniform ECP standard. HHS achieves this outcome by soliciting qualified ECPs throughout the vear to complete and submit the ECP application in order to be added to the HHS ECP list or update required data fields to remain on the list. In soliciting updates directly from providers, HHS routinely performs research and outreach to providers on the ECP List to verify information about ECPs collected via the ECP application and annual renewal form. These ongoing efforts will

result in a more accurate listing of the universe of available ECPs from which issuers select to satisfy the ECP standard. Form Number: CMS-10561 (OMB control number: 0938-1295); Frequency: Annually; Affected Public: Private Sector—Business or other forprofits and Not-for-profits institutions; Number of Respondents: 19,020; Number of Responses: 19,020; Total Annual Hours 4,913.75. (For questions regarding this collection, contact Samantha Nguyen Kella at 816-426-6339).

3. Type of Information Collection Request: New collection (Request for a new OMB control number); Title of Information Collection: 13th SOW QIN-QIO and AI/AN Advancing Healthcare Quality through Technology (AHQT) Readiness Assessment; Use: This is a new information collection request. The Quality Improvement Network—Quality Improvement Organization (QIN–QIO) program and American Indian/Alaska Native (AI/AN) program assists providers/practices with high-quality, hands-on quality improvement assistance toward meeting their needs, and the healthcare quality and safety goals for beneficiaries. The purpose of this new information collection within these programs is to assess the readiness of participating nursing homes, hospitals, outpatient clinical practices, and AIAN facilities to access, share, and use data electronically for quality improvement and quality reporting. Use of health information technology (HIT) is imperative to assess, monitor, and improve healthcare quality, patient safety, and care coordination.

Many providers/practices continue to lack basic knowledge and capacity to implement HIT to support data exchange between providers/practices, payers, and patients, and to use data for improving quality and outcomes. This "digital divide" creates burden for patients, families, caregivers, providers/ practices and increases costs and administrative waste. This burden is disproportionate for underserved populations. Advancing the use of technology and using interoperable standards can reduce the overall cost and burden associated with data collection and supports communication across the care continuum and is an agency priority.

CMS has developed a 41-item Assessment of Health care Quality Technical Readiness (AHQT) for use with participating providers/practices under the QIN–QIO 13th SOW. Provider/practice burden associated with the collection and reporting of quality measurement data has historically been a pain point for the

QIN–QIO and AI/AN programs, especially in outpatient clinical practices and critical access hospitals; this burden has been a barrier to both achievement of quality improvement contract goals and proper evaluation of their impact.

The results of the assessment will be used to determine which providers/ practices may benefit from participation in a technical assistance pilot specific during the QIN-QIO 13th SOW intended to advance provider/practice capacity for engaging in quality improvement and reporting activities facilitated by HIT. Form Number: CMS-10916 (OMB control number: 0938-NEW); *Frequency:* Occasionally; Affected Public: Private Sector (Business or other for-profit and Not-for-profit institutions); Number of Respondents: 53,000; Total Annual Responses: 10,600; Total Annual Hours: 10,600. (For policy questions regarding this collection contact Geoffrey Berryman at 410-299-7390).

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

Food and Drug Administration [Docket No. FDA-2019-N-1875]

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug
Administration (FDA or the Agency) is
announcing the following public
meeting entitled "Financial
Transparency and Efficiency of the
Prescription Drug User Fee Act,
Biosimilar User Fee Act, and Generic
Drug User Fee Amendments." The topic
to be discussed is the financial
transparency and efficiency of the
Prescription Drug User Fee Act,
Biosimilar User Fee Act, and Generic
Drug User Fee Amendments.

DATES: The public meeting will be held on September 30, 2025, from 9:30 a.m. to 10:40 a.m. via Microsoft Teams. Either electronic or written comments