Industry and Food and Drug Administration Staff'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Mahlet Zinah, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4452, Silver Spring, MD 20993–0002, 240–402–2623.

SUPPLEMENTARY INFORMATION:

I. Background

Non-spinal, non-resorbable bone plates, screws, and washers are implants intended for bone fixation. These are class II medical devices for which the safety and effectiveness are well-established. This guidance provides recommendations for the content and organization of premarket notification (510(k)) submissions including the information FDA recommends industry include in a 510(k) submission for these device types (*e.g.,* non-clinical testing, sterility, reprocessing, biocompatibility). This guidance is intended to facilitate consistency in information provided in submissions by addressing common deficiencies related to device description and performance testing and by identifying applicable cross-cutting guidances and consensus standards.

A notice of availability of the draft guidance appeared in the **Federal Register** of March 29, 2023 (88 FR 18549). FDA considered comments received and revised the guidance as appropriate in response to the comments, including clarification regarding recommended language for indications for use statements as well as additional considerations for predicate device comparisons when leveraging information from previously cleared devices.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k)) Submissions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov* and *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Persons unable to download an electronic copy of ''Non-Spinal Bone Plates, Screws, and Washers—Premarket Notification (510(k)) Submissions; Guidance for Industry and Food and Drug Administration Staff'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00019023 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in the following table have been approved by OMB:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
812	Investigational Device Exemption	0910–0078
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions and Early Payor Feedback Request Programs for Medical Devices.	0910–0756
800, 801, 809, and 830	Medical Device Labeling Regulations; Unique Device Identification.	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation.	0910–0073
50, 56	Protection of Human Subjects and Institutional Review Boards	0910–0130

Dated: November 12, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–27114 Filed 11–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Health Resources and Services Administration Uniform Data System

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

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than January 21, 2025.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14NWH04, 5600 Fishers Lane, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the

proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443–3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Health Resources and Services Administration (HRSA) Uniform Data System (UDS), OMB No. 0915–0193—Revision.

Abstract: The Health Center Program, administered by HRSA, is authorized under section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b). Health centers are community-based and patient-directed organizations that deliver affordable, accessible, quality, and cost-effective primary health care services to patients regardless of their ability to pay. Nearly 1,400 health centers operate approximately 15,500 service delivery sites that provide primary health care to more than 31 million people in every U.S. state, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, and the Pacific Basin.

HRSA uses the UDS for annual reporting of program-specific data by Health Center Program awardees (those funded under section 330 of the PHS Act), Health Center Program look-alikes (entities meeting requirements of, but not funded under, section 330 of the PHS Act), and Nurse Education, Practice, Quality and Retention (NEPQR) and Advanced Nursing Education (ANE) Program awardees (specifically those funded under the practice priority areas of sections 831(b) and 811 of the PHS Act).

Some NEPQR and ANE Program awardees establish and expand nursing practice arrangements in noninstitutional settings to demonstrate methods to improve access to primary health care in medically underserved communities. Nursing grantees implementing nursing practice arrangements have historically used the same data collection system as the Health Center Program.

Need and Proposed Use of the Information: HRSA requires the collection of information through UDS to monitor and evaluate the performance of health centers under section 330 and select NEPQR and ANE recipients under sections 831(b) and 811. These data aid in program compliance, guide quality improvement initiatives, and inform federal health policy decisions. HRSA also leverages UDS data to assess the impact of health centers and NEPQR and ANE recipients on patient health outcomes and to allocate funding and resources effectively across the Health Center Program. To keep this instrument relevant and responsive to the health center program's needs and the evolving healthcare landscape, periodic updates are essential. HRSA plans to make the following updates for the performance year 2025 UDS data collection:

Table 6A (Selected Diagnoses and Services Rendered) Additions

- *Tobacco Use Cessation Pharmacotherapies:* A new measure is being added to line 26c2 to identify the number of visits where patients received tobacco cessation pharmacotherapies as an intervention and the number of patients who received this pharmacologic treatment. While the Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention electronic-specified clinical quality measures (CMS138v12) (Table 6B, Line 14a) that is currently reported in the UDS assesses for cessation, it lacks the capacity to disaggregate and report a distinct percentage for patients receiving counseling or recommendation to cessation pharmacotherapies. Adding a line for reporting of tobacco use cessation pharmacotherapies will promote greater understanding of the breadth of tobacco cessation interventions provided at health centers, specifically allowing HRSA to see differences in tobacco use cessation approaches.
- *Medications for Opioid Use Disorder (MOUD):* A new measure for MOUD services will be reported on line 26c3 for the number of visits where MOUD was administered and the number of patients who received this medication-based intervention. This new measure will enhance the existing MOUD related measures that health centers currently report on in Appendix E: Other Data Elements (*e.g.,* number of providers who treat opioid use disorder with MOUD). The inclusion of this measure is critical for supporting public health efforts to address the ongoing opioid epidemic. Greater understanding of the use of MOUD in health centers is necessary both to understand existing services and identify remaining healthcare gaps.
- *Alzheimer's Disease and Related Dementias (ADRD) Screening:* A new measure is being added to line 26f to capture the number of visits where patients received ADRD screenings and the number of patients who received the screenings. This measure will encompass assessments representing standardized tools used for the evaluation of cognition and mental status of older adults. The addition of a measure to capture screening of ADRD will be valuable in understanding the level of need and resources required to continue to support the growing aging population served by the Health Center Program and will foster early detection for those at risk for ADRD.

Table 6B (Quality of Care Measures) Addition

- *Initiation and Engagement of Substance Use Disorder Treatment:* A new measure with two distinct rates is being added to Lines 23a and b to capture the initiation and engagement of substance use disorder treatment, in alignment with electronic-specified clinical quality measure CMS137v13. This measure will report on the percentage of patients 13 years and older with a new substance use disorder episode who received treatment, including (a) those who initiated treatment within 14 days and (b) those who engaged in ongoing treatment within 34 days. By incorporating this measure, HRSA strengthens its alignment with national performance standards and gains greater insight into how effectively health centers are initiating and engaging patients in substance use disorder treatment.

Table 6B (Quality of Care Measures) and Table 7 (Health Outcomes and Disparities)

Updates

- Tables 6B and 7 collect UDS clinical quality measures,[1] and where applicable, clinical quality measures will be updated in alignment with specifications of the issued performance year 2025 electronic-specified clinical quality measures. These specifications were released by the Centers for Medicare and Medicaid Services (CMS) on May 2, 2024, for use by eligible providers.[2] Clinical performance measure alignment across national programs promotes data standardization, quality, and transparency, and decreases reporting burden for providers and organizations participating in multiple federal programs.

[1] *https://www.cms.gov/medicare/quality/measures.*

[2] *https://ecqi.healthit.gov/now-available-updated-ecqm-specifications-and-implementation-resources-2025-performance/reporting-period.*

UDS+ Test Submissions for Health Centers

- Beginning with the 2024 UDS, health centers will be able to submit de-identified, patient-level data in fulfillment of data elements on Tables:
  - Table PBZC (Patients by ZIP Code)
  - Table 3A (Patients by Age and Sex Assigned at Birth)
  - Table 3B (Demographic Characteristics)
  - Table 4 (Selected Characteristics)
  - Table 6A (Selected Diagnoses and Services Rendered)
  - Table 6B (Quality of Care Measures)
  - Table 7 (Health Outcomes and Disparities

UDS+ Patient-Level Reporting leverages a shift in processes by which health centers will submit their annual UDS reports while maintaining historic UDS measures. Health Centers are encouraged to submit data through UDS+.

UDS+ is currently in the testing phase and data submission supports system capacity building and progress towards full implementation. The technical test will inform next steps for scaling this innovation. High-quality accessible data are critical to strategically meeting the unique needs of health center patients and identifying training and technical assistance opportunities for clinical process improvement. The growth in health information technology coupled with the near universal adoption of electronic health records across health centers has transformed patient care delivery and underscored the need for secure and rapid exchange of health data between disparate systems. Fast Healthcare Interoperability Resources® is a Health Level Seven International® standard for exchanging health care information electronically.[3] The health care community is adopting this next generation exchange framework to advance interoperability.[4] Leveraging Fast Healthcare Interoperability Resources® to collect patient-level data through the UDS+ system will support improved data granularity, allowing for the development of robust HRSA-supported patient care programs and improved equitable access to HRSA-supported high-quality, cost-effective primary care services. This electronic reporting mechanism will reduce reliance on manual data entry to populate the annual UDS report, in turn yielding a reduction in reporting effort burden, and will greatly increase the analytical value of UDS data for informing policy and program decision-making.

Likely Respondents: Respondents will include Health Center Program award recipients and Health Center Program look-alikes carrying out programs under section 330 of the PHS Act and NEPQR and ANE award recipients funded under the practice priority areas of section 831(b) and 811 of the PHS Act.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total burden hours
Universal Report	* 1,538	1.00	238	366,044
Grant Report	** 420	1.22	22	11,273
UDS+ Test Submissions	1,507	1.25	10	18,838
Total	3,465		270	396,155

* Consists of 1,363 health center program awardees, 133 Health Center Look-alikes, and 42 NEPQR and ANE respondents.
** Health Centers submitted one or more grant reports in 2023: 339 (1 report), 70 (2 reports), 11 (3 reports).

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–27394 Filed 11–21–24; 8:45 am]

BILLING CODE 4165–15–P

[3] *https://ecqi.healthit.gov/fhir.*

[4] *https://ecqi.healthit.gov/fhir.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Notice of Purchased/Referred Care Delivery Area Redesignation for the Pokagon Band of Potawatomi Indians of Michigan and Indiana

AGENCY: Indian Health Service, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Indian Health Service (IHS) has decided to expand the geographic boundaries of the Purchased/Referred Care Delivery Area (PRCDA) for the Pokagon Band of Potawatomi Indians of Michigan and Indiana (''Pokagon Band'') to include the counties of Kalamazoo, Kent, and Ottawa in the State of Michigan. The final PRCDA for the Pokagon Band now includes the Michigan counties of Allegan, Berrien, Cass, Kalamazoo, Kent, Ottawa, and Van Buren, and the Indiana counties of Elkhart, Kosciusko, La Porte, Marshall, St. Joseph, and Starke. The sole purpose of this expansion is to authorize additional Pokagon Band members and beneficiaries to receive Purchased/Referred Care (PRC) services.

DATES: This expansion is effective as of the date of publication of this notice.

ADDRESSES: This notice can be found at *https://www.federalregister.gov.* Written requests for information should be delivered to: CAPT John Rael, Director,