: 4165-15-P

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; 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 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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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 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) 443-3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: 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 required 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 areas with unmet primary health care needs. Such grantees implementing nursing practice arrangements have historically used the same data collection system as the Health Center Program for their required annual reporting of program-specific data.

A 60-day notice was published in the *Federal Register* on November 22, 2024 (89 FR 92692-94). There were 18 public comments. Below is a summary of key themes raised in the comments and HRSA's response:

- Many stakeholders expressed strong support for the proposed addition of UDS measures and collection, acknowledging their potential to enhance care quality and patient

outcomes;

- Stakeholders sought clarification on how to accurately report on the proposed measures;
- Others leveraged the Federal Register notice comment period as an opportunity to propose new measures in the UDS instrument;
- Some commenters expressed concerns about the potential increase in reporting burden associated with the proposed changes, particularly for health centers without designated Health Informaticists; and
- Several commenters recommended expanding upon 2025 UDS proposed measures in a future ICR to include mechanisms for assessing the outcomes of proposed interventions.

HRSA directly responded to each stakeholder who submitted comments, acknowledging the considerations raised and committed to the continued evaluation and exploration of downstream implications for the proposed 2025 UDS changes. There will be opportunities for stakeholders to propose new measures for consideration in future instruments. HRSA did not make any changes to the ICR in response to comments received.

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 primary healthcare and clinical measurement landscape, periodic updates are essential. Updates for the performance year 2025 UDS data collection include:

Table 3B (Demographic Characteristics) Updates:

- **Removal of Patients by Sexual Orientation and Gender Identity:** Data elements

related to sexual orientation and gender identity will be removed to align with Administration priorities.

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 measure (CMS138v12) (Table 6B, Line 14a) that is currently reported in the UDS assesses for cessation, the way the measure is specified for reporting by its measure steward does not allow the disaggregation for the percentage of patients receiving counseling or recommendation to cessation pharmacotherapies. Adding a unique UDS line for reporting 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 complement and enhance the existing MOUD-related measures currently reported 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 enhancing efforts to address the ongoing opioid epidemic. Additional examination of the use of MOUD in health centers is necessary to better understand existing services and identify potential 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 this 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 of 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 of the initiation. By incorporating this measure, HRSA strengthens its alignment with national performance standards and gains greater insight into health centers' effectiveness in initiating and engaging patients in substance use disorder treatment.

Table 6B (*Quality of Care Measures*) and Table 7 (*Health Outcomes*) 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 & Medicaid Services on May 2, 2024, for use by eligible providers.[2] Clinical performance measure alignment across national programs promotes data standardization, quality, and transparency, and

[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

decreases reporting burden for providers and organizations participating in multiple federal programs.

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	Number of Respondents*	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Universal Report	1,538.00	1.00	1,538.00	238	366,044.00
Grant Report	420.00	1.22	512.40	22	11,272.80
Total	1,958.00	--	2,050.40	--	377,316.80

* The estimated number of respondents for the Universal Report consists of 1,363 Health Center Program awardees, 133 Health Center Look-alikes, and 42 NEPQR and ANE respondents. The estimated number of respondents for the "Grant Report" is based on the number of reports submitted by health centers in 2024: 339 (1 report), 70 (2 reports), 11 (3 reports).

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