

## **Supporting Statement A**

### **Health Resources and Service Administration Uniform Data System**

**OMB Control No. 0915-0193**

**Terms of Clearance:** None

#### **1. Circumstances Making the Collection of Information Necessary**

The Health Resources and Services Administration (HRSA) is requesting OMB approval for the revision of forms used to collect data in the Uniform Data System (UDS). HRSA utilizes the UDS for the required annual reporting by Health Center Program awardees (those funded under section 330 of the Public Health Service (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). The UDS forms are currently approved under OMB Control No. 0915-0193, and the current expiration date is April 30, 2026.

To keep the UDS instrument relevant and responsive to the Health Center Program's needs and the evolving healthcare landscape, HRSA will implement changes for the performance year 2025 UDS data collection. This includes no longer collecting information related to sexual orientation (SO) and gender identity (GI), and changes to the collection of data related to tobacco use cessation pharmacotherapies, medications for opioid use disorder (MOUD), Alzheimer's Disease and Related Dementias (ADRD), substance use disorder (SUD) treatment and engagement, as well as continued alignment of clinical quality measures to electronic specifications. These updates have led to the need to update the UDS instrument, and in turn, the performance reporting requirements.

HRSA is proposing the following modifications to the UDS:

*1. Update to Table 3B: Removal of 'Patients by Sexual Orientation' and 'Patients by Gender Identity' indicators*

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

*2. Addition to Table 6A: Selected Diagnoses and Services Rendered, to include a new Tobacco Use Cessation Pharmacotherapies measure 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.*

The addition 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.

*3. Addition to Table 6A: Selected Diagnoses and Services Rendered, to include a new Medications for Opioid Use Disorder (MOUD) measure to capture the number of visits where MOUD was administered and/or prescribed and the number of patients who received this medication-based intervention.*

This addition will complement and 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 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.

*4. Addition to Table 6A: Selected Diagnoses and Services Rendered, to include a new Alzheimer's Disease and Related Dementias (ADRD) Screening measure to capture the number of visits where patients received ADRD screenings and the number of patients who received the screenings.*

This addition 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.

*5. Addition to Table 6B: Quality of Care Measures, to track the number of patients 13 and older with a new substance use disorder who initiated and engaged in substance use disorder treatment.*

The addition of this measure will allow HRSA to strengthen its alignment with national performance standards and gain greater insight into health centers' effectiveness in initiating and engaging patients in substance use disorder treatment.

*6. Alignment of Quality of Care Measures with the Centers for Medicare and Medicaid Services (CMS) electronic-specified clinical quality measures (eCQMs) for the 2025 calendar year reporting. These include the following:*

1. Childhood Immunization Status has been revised to align with [CMS117v13](#).
2. Cervical Cancer Screening has been revised to align with [CMS124v13](#).
3. Breast Cancer Screening has been revised to align with [CMS125v13](#).
4. Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents has been revised to align with [CMS155v13](#).
5. Preventive Care and Screening: Body Mass Index Screening and Follow-Up Plan has been revised to align with [CMS69v13](#).
6. Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention has been revised to align with [CMS138v13](#).
7. Statin Therapy for the Prevention and Treatment of Cardiovascular Disease has been

- revised to align with [CMS347v8](#).
8. Colorectal Cancer Screening has been revised to align with [CMS130v13](#).
  9. HIV Screening has been revised to align with [CMS349v7](#).
  10. Preventive Care and Screening: Screening for Depression and Follow-Up Plan has been revised to align with [CMS2v14](#).
  11. Depression Remission at Twelve Months has been revised to align with [CMS159v13](#).
  12. Controlling High Blood Pressure has been revised to align with [CMS165v13](#).
  13. Diabetes: Hemoglobin A1c (HbA1c) Poor Control (> 9%) has been revised to align with [CMS122v13](#), and is now referred to as [“Diabetes: Glycemic Status Assessment Greater than 9%.”](#)

Clinical performance measure alignment across national programs promotes data standardization and quality and decreases reporting burden.

## 2. Purpose and Use of Information Collection

HRSA requires the collection of information through UDS to monitor and evaluate the performance of health centers under section 330, Health Center Program look-alikes, 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 these programs. To keep this instrument relevant and responsive to the Health Center Program’s needs and the evolving health care landscape, periodic updates are essential.

One concrete example of how UDS data has been used in quality improvement efforts is with the identification of expanded opportunities for targeted technical assistance related to the management of chronic conditions among health center patients. For instance, one of the primary inclusion criteria for the selection of health centers for participation in the National Hypertension Control Initiative (NHCI) was UDS ranking of a health center with less than 50% hypertension control among their patients with hypertension. This UDS data point in combination with HIT capability, patient health/digital literacy, and workforce (care team) support allowed for the development of technical assistance that over 2.5 years resulted in national hypertension control rates incrementally increasing from 2020 to 2023 (57.98% to 65.68%) and NHCI hypertension control rates similarly improved from Quarter 3 of 2022 to Quarter 4 of 2023 (24.5% to 45.0%). This use case of UDS data highlights the importance of ensuring that updates not only address program priorities but also drive meaningful improvements in health center performance.

Further, UDS data are compared with national health-related data and benchmarks to explore potential differences between health center patient populations and the U.S. population at-large. Comparisons to national data and benchmarks include the National Health Interview Survey<sup>1</sup>,

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<sup>1</sup> <https://www.cdc.gov/nchs/nhis/index.htm>

National Health and Nutrition Examination Survey<sup>2</sup>, Healthy People 2020 and 2030<sup>3</sup> objectives, and the Centers for Disease Control and Prevention's Million Hearts<sup>4</sup> initiative.

Data elements collected within the UDS rely on self-attestation by the health center staff responsible for submission. Health centers are required to certify, to the best of their knowledge and belief, that the data reported are true, accurate, and complete. This certification process is conducted through HRSA's Electronic Handbooks grants management system, where health centers formally attest to the validity of their submissions prior to final report submission. If a health center fails to comply with Federal statutes, regulations, or the terms and conditions of a Federal award, including the timely, accurate, and complete submission of UDS data, HRSA may impose conditions on the federal award, including the suspension and/or debarment of the health center. In addition, failure to submit a complete UDS report by the specified deadline may result in conditions or restrictions being placed on a Health Center's award, such as requiring prior approval of drawdowns of Health Center Program award funds and/or limiting eligibility to receive future base and/or supplemental funding.

### **3. Use of Improved Health Information Technology and Burden Reduction**

The data collection plan for HRSA's UDS has been designed to streamline data reporting and minimize respondent burden by aligning measures with standardized formats and leveraging health centers' health information technology (HIT) and electronic health records (EHRs) for efficient data extraction. Advancements in EHR technology have been proceeding at a rapid pace. HIT can help health centers achieve quality and efficiency goals, and the use of EHRs streamlines and simplifies health center reporting of UDS measures. At present, 99% of health centers have EHRs installed. Broader adoption of EHR systems has furthered the need to share data across settings, providers, and networks to support care quality and patient outcomes. The integration of these electronic systems decreases the time and effort that would be required to complete manual data extraction for reporting UDS data.

### **4. Efforts to Identify Duplication and Use of Similar Information**

The information collected by these forms is unique to the above-referenced programs. Information is not captured in the same form and format elsewhere. There are no other existing sources that could be used for monitoring performance and administration of HRSA's Health Center and NEPQR/ANE Programs.

### **5. Impact on Small Businesses or Other Small Entities**

This activity does not have a substantial impact on small entities or small businesses. Though, recognizing that healthcare providers may be considered small businesses, HRSA is committed to limiting the reporting burden associated with UDS submissions. Efforts to reduce this burden include streamlining data collection processes through the integration of electronic health records

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<sup>2</sup> <https://www.cdc.gov/nchs/nhanes/index.htm>

<sup>3</sup> <https://health.gov/healthypeople>

<sup>4</sup> <https://millionhearts.hhs.gov/>

to report on electronically specified clinical quality measures, offering comprehensive technical assistance, and providing clear guidance to ensure efficient and accurate reporting. These measures, in addition to those identified in question three, are designed to support small entities in meeting reporting requirements with minimal disruption operations.

## **6. Consequences of Collecting the Information Less Frequently**

UDS data are required to be submitted by health centers and certain NEQPR and ANE recipients once, annually to effectively monitor program performance, assess emerging trends and respond to changing health care needs promptly, and administer program funds. For look-alikes, UDS data are used to monitor program performance and for designation and recertification decisions. While less frequent reporting might appear to reduce burden, it could instead increase challenges as health centers and certain NEQPR and ANE recipients may need to reconstruct data for longer periods, leading to potential inaccuracies, increased workload, or knowledge transfer gaps.

## **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

HRSA intends to track with the Centers for Medicare & Medicaid Services (CMS), which currently plans to implement SPD-15-compliant standards by 2027. This alignment is especially important given that several UDS clinical quality measures are directly mapped to CMS' Adult and Child Core Sets, as well as measures used in CMS' Quality Payment Programs and other adopted initiatives. This timeline is consistent with the federal requirement that agencies come into compliance with SPD-15 by 2029.

Further, HRSA is currently working with health centers and health information technology vendors supporting health centers to meet the additional reporting requirements resulting from revisions to SPD-15. Existing EMR and practice management systems are working to accommodate the revised standards, including necessary programming updates to allow for the changes in information architecture to user interface, expanded drop-down menu selections, and re-organized reporting structures. These considerations may necessitate additional time for intake and clinical workflows to adhere to compliance with SPD-15 requirements and impact UDS reporting.

Accordingly, HRSA anticipates incorporating the SPD-15-compliant standards into the UDS beginning with the 2027 reporting year, consistent with CMS's implementation timeline and ahead of the final 2029 compliance deadline. In the interim, HRSA will continue to support health centers in expanding their data collection capabilities, improving data quality, and preparing for future compliance with SPD-15.

## **8. Comments in Response to the Federal Register Notice/ Outside Consultation**

### **Section 8A: Comments in Response to the Federal Register Notice**

Preceding OMB review, a 60-day Federal Register notice was published on 11/22/2024 for public comment with a close period of 01/21/2025. The 60-day FRN was published in the *Federal Register*, volume 89, No. 226; pp. 92692-92694. HRSA received 18 comments.

Comments received from the 60-day FRN included requests for clarification on reporting requirements for newly introduced measures. Specifically, commenters sought greater detail on the definitions used for reporting purposes, such as the interpretation of “treatment” in the context of calculating measure numerators and denominators. Additionally, some respondents emphasized the importance of aligning reporting expectations with USPSTF clinical guidelines and recommendations, particularly for Alzheimer’s Disease and Related Dementias screening where routine screening is not clinically indicated.

Further, commenters requested guidance on how to accurately document patient encounters and treatments in electronic medical records (EMRs) when care occurs outside the health center setting. The need for standardized reporting practices to ensure consistency while minimizing reporting burden was underscored. These comments reflect a focus on ensuring clarity, high-quality and robust training and technical assistance, reducing burden, and maintaining alignment with evidence-based clinical standards.

No comments were received proposing specific changes to the measures themselves. Instead, feedback focused on the need for clarification on how to accurately and consistently report on these measures. As is standard practice each year, these clarifications will be addressed through the issuance of detailed technical guidance in the UDS Manual, as well as targeted technical assistance, following the approval of the final UDS measurement changes.

### **Section 8B: Outside Consultation**

During UDS measurement development, input on the instrument’s content and wording was sought from fewer than 10 subject matter experts. HRSA also consulted on the availability of data, the clarity of instructions and record keeping, disclosure, reporting format, and on the data elements to be recorded and reported. HRSA has ongoing engagements with a contractor and health center stakeholders. Stakeholders represent individuals with expertise in health center operations, clinical quality reporting, and data management. Cooperative agreement relationships, such as Primary Care Associations, Health Center Controlled Networks, and National Training and Technical Assistance Partners, are also leveraged for stakeholder input. Input is used to assess the appropriateness of proposed new measures for the UDS instrument, ensuring the burden associated with implementing these measures remains minimal and manageable.

## **9. Explanation of any Payment/Gift to Respondents**

Respondents will not receive any payments or gifts; reporting is a requirement of their Health Center Program funding and to maintain designation as a look-alike. Additionally, NEQPR and ANE recipients are prohibited from receiving any gifts or payments in exchange for submitting UDS data.

## **10. Assurance of Confidentiality Provided to Respondents**

Given its current state of reporting at the aggregate level, the UDS does not involve the reporting

of personally identifiable information about individuals. Data will be kept private to the extent allowed by law.

## 11. Justification for Sensitive Questions

The UDS is designed to extract data from existing medical records rather than through direct patient questioning or interviews. Data elements included in the instrument, such as those related to alcohol or drug use, are derived from standardized coding systems, including Current Procedural Terminology (CPT) and International Classification of Diseases (ICD) codes, which are documented during clinical care. As such, the information is based on provider-recorded diagnoses and services rather than responses to specific questions posed directly to patients. HRSA utilizes UDS data that may be sensitive in nature (i.e., substance use disorder) to guide resource allocation and funding opportunities, in addition to measure health center performance in key quality measures related to substance use disorder care and treatment.

## 12. Estimates of Annualized Hour and Cost Burden

### 12a. 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).

The burden estimates for completing the UDS have been determined based on the experience of HRSA, factoring in minor modifications proposed by commenters and feedback received from outside consultation and key stakeholders. For 2024 UDS reporting, HRSA estimates that there were approximately 1,538 respondents for completing the Universal Report and 420 for completing the Grant Report. For this collection, respondents are defined as the entity receiving HRSA funding or designation. HRSA is requesting that the organization respond, not an individual person for themselves.

The UDS report is completed by all Health Center Program award recipients, look-alikes, and – certain NEPQR and ANE award recipients. The Universal Report is completed by all awardees and look-alikes, and the Grant Award Report is completed by a subset of awardees, who receive

multiple grant awards. Look-alikes DO NOT receive regular federal funding under section 330 of the PHS Act (although they may receive funding during public health emergencies, such as COVID-19), but meet the Health Center Program requirements for designation under the program (42 U.S.C. 1395x<sup>5</sup> (aa)(4)(A)(ii) and 42 U.S.C. 1396d(l)(2) (B)(ii)).

The average burden per response, for completing the Universal Reporting is estimated to take 238 hours and an estimated 22 hours for the Grant Report.

The Grant Report is completed by a subset of Health Center Program award recipients<sup>6</sup> who receive funding to serve migratory and seasonal agricultural workers, funding to serve homeless populations, and funding to serve residents of public housing. These grant reports are a subset of the universal report and are estimated to take 22 hours to complete. Organizations that receive multiple funds are required to report on the different populations they serve.

#### 12b.

The forms are expected to be completed by a Medical Records Specialist, who has a median hourly wage of \$24.16 per hour. This amount is multiplied by 2 to adjust for overhead benefits, for a total hourly median wage of \$48.32.

#### Estimated Annualized Burden Costs:

| Form Name        | Estimated Number of Respondents | Type of Respondent                      | Average Total Burden Hours | Hourly Median Wage | Estimated Total Respondent Costs |
|------------------|---------------------------------|---|----------------------------|--------------------|----------------------------------|
| Universal Report | 1,538                           | Medical Records Specialist <sup>7</sup> | 366,044.00                 | \$48.32            | \$17,687,246.080                 |
| Grant Report     | 420                             | Medical Records Specialist              | 11,272.80                  | \$48.32            | \$544,701.696                    |
| Total            | 1,958                           |   | 377,316.80                 |                    | \$18,231,947.776                 |

### 13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

Health center respondents may incur additional annual operation and maintenance costs for programming or re-programming their health information technology systems to generate data in the required UDS reporting format.

### 14. Annualized Cost to the Federal Government

The estimated annual cost to the government for contracts providing technical assistance and data reporting support, data processing, editing, and verification is \$3,000,000. Additionally,

<sup>5</sup> [https://uscode.house.gov/view.xhtml?req=\(title:42%20section:1395x%20edition:prelim\)](https://uscode.house.gov/view.xhtml?req=(title:42%20section:1395x%20edition:prelim))

<sup>6</sup> <https://data.hrsa.gov/tools/data-reporting/special-populations>

<sup>7</sup> <https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm>.



UDS reporting is supported by a team of FTEs, where a portion of their time is dedicated to UDS. The estimated annual cost to the government for this composition of FTE time is \$427,644 and through another contract, about \$3,000,000 to support the IT Systems programming, testing, and interface currently used by health centers to submit annual UDS reports. Total estimated annual costs to the government are \$6,427,644

## **15. Explanation for Program Changes or Adjustments**

In 2025, the estimated total burden hours for this ICR are approximately 377,317 hours, compared to 2023 where the burden was estimated to be 375,324 hours—an increase of approximately 1,993 hours collectively across health centers or an average of 1.3 hours per health center. This increase is primarily due to the growing number of newly added health centers to the Health Center Program that are now required to submit UDS data, reflective of HRSA’s broader efforts to expand access to primary care services across areas with unmet primary health care needs. This marginal increase in the overall burden hours does not reflect a change in the reporting requirements or the complexity of the UDS submission. Rather, the increase results from the addition of new health centers funded under the HCP, which has led to a larger pool of reporting entities.

## **16. Plans for Tabulation, Publication, and Project Time Schedule**

Respondents submit their information between January 1 and February 15 of the calendar year and report on patient demographics, clinical measures, and financials related to primary care services provided to patients served by health centers and ANE and certain NEPQR recipients over the previous calendar year. For example, 2024 UDS data were reported January 1 through February 15 of 2025. From February 15 to March 31, UDS reports are reviewed for data quality and consistency. Statistical analyses are conducted with the information collected. Please see Supporting Statement B for more detailed information. Summary descriptive reports of the information collected have historically been prepared and published by August of the calendar year to HRSA’s data website: <https://data.hrsa.gov/tools/data-reporting>.

## **17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The OMB number and expiration date will continue to be displayed on the back cover of the UDS Manual’s electronic file.

## **18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.