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Supporting Statement

Health Resources and Services Administration: Uniform Data System

OMB Control No. 0915-0193

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Terms of Clearance: None

A.   Justification

1.   Circumstances Making the Collection of Information Necessary

        This is a request for a revision of OMB approval to collect a revised Uniform Data System (UDS), the annual reporting requirement for health centers funded under Section 330 of the Public Health Service (PHS) Act. The Health Resources and Services Administration (HRSA) is responsible for the administration of the Health Center Programs under Section 330. HRSA also is responsible for administering the FQHC Look-Alike Program, which is comprised of health centers that meet the requirements of the Health Center Program but which do not receive a grant. The UDS was approved under OMB No. 0915-0193 and expires on 2/28/2015.

The significant growth of the Health Center Program, the advent of incentive-based payment for performance initiatives, and the proliferation of health information technology (HIT) enhancements within health centers are major factors which have heightened the need to evaluate and revise the performance reporting requirements of the Health Center Program. As health centers receive reimbursement and support through multiple funding streams, improving performance reporting can also reduce the reporting burden by aligning health center reporting requirements on clinical performance measures with those of major national quality improvement organizations. Furthermore, enhanced performance reporting will result in the ability to make evidence-based statements about the impact of the Health Center Program on improving access to cost-effective primary care to the nation's underserved populations.

Three modifications to the UDS are proposed for 2015: reporting dually eligible Medicare and Medicaid patients, reporting dental sealants in children, and a revision to the diabetes control measure.

  1. Patient Characteristics

        Table 4 – The number of dually eligible Medicare and Medicaid patients is reported on table 4, line 9a.

        Rationale: Currently the UDS does not capture dual (Medicaid and Medicare) beneficiaries. The Bureau of Primary Health Care is anticipating growth in older adult patients for the Health Center Program as a result of an aging US population. Given that health centers serve a large proportion of patients living in poverty, it is likely

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that older adult patients that will be cared for by health centers will be dual beneficiaries. Collection of dual beneficiaries data will provide more specific information on health center patients to improve the responsiveness of care delivery and for targeted technical assistance on health center quality improvement initiatives.

2. *Quality of Care Measures*

   Table 6B – The number of children age 6-9 years at "elevated" risk for cavities who received a dental sealant on a permanent first molar tooth is reported on table 6B, line 22.

   Rationale: Oral health improvement and integration of oral health into primary care are HRSA priorities. Dental sealants act as a barrier to prevent cavities. This oral health measure has been scientifically demonstrated to prevent 60% fewer new decays and is endorsed by the National Quality Forum (NQF)

3. *Health Outcomes and Disparities Measures*

   Table 7 – Health Outcomes and Disparities has been modified by revising the diabetes control measure to no longer require reporting for 8% <= HbA1c <= 9%. Only collect and report on Hba1c < 8% and HbA1c > 9%.

   Rationale: Revision of the UDS diabetes control measure supports HRSA BPHC's clinical quality improvement initiatives and improves measurement alignment with the National Quality Forum (NQF). HbA1c > 9% is an indicator of poor diabetes control and aligns with Healthy People 2020. The HP 2020 objective is to "reduce the proportion of persons with diabetes with an HbA1C > 9%."

Health Center Program Scope

The Bureau of Primary Health Care (BPHC) in HRSA has the responsibility for and oversight of programs designed to provide health services to medically underserved and vulnerable populations. These populations include the poor and near poor, migratory and seasonal agricultural workers, the homeless, and residents of public housing. The overall mission is to improve the health of the Nation's underserved communities and vulnerable populations by assuring access to comprehensive, culturally competent, quality primary health care services.

Health centers receive funding and support from a variety of sources, and HRSA grant dollars represent approximately 20% of health center revenues.   Federally qualified health centers include centers that receive federal grants under Section 330 of the PHS Act and centers that qualify for special payment rates from Medicare and Medicaid because they meet the 330 grant requirements.

The term "health center" refers to a variety of different organizations and programs covered by subsections of Section 330 and the Health Center Program. There is no "model" for health centers, yet all health centers share similar attributes, including the goal of providing quality primary and preventive health care services to underserved populations.

These populations face great barriers in accessing and obtaining primary and preventive services. Health centers form an integrated safety net for underserved and uninsured children, adults, agricultural workers, homeless individuals, and public housing residents. Nearly 22 million people are served annually by health centers that would otherwise lack access to primary care providers.

The UDS is the annual reporting requirement for HRSA grantees that receive funding under the following primary care programs:

- Community Health Center Program, Section 330(e) of the Public Health Service Act

- Migrant Health Center Program, Section 330(e) of the Public Health Service Act

- Health Care for the Homeless Program, Section 330(h) of the Public Health Service Act

- Public Housing Primary Care, Section 330 (i) of the Public Health Service Act

Annual data are required from these grantees to ensure compliance with legislative mandates, to report to Congress and policy makers on program accomplishments and performance, and to prepare HRSA's annual performance plan and budget. Similarly, annual data are required from Health Center Program look-alikes (or look-alikes) to ensure compliance with legislative mandates and to report to Congress and policy makers on program accomplishments and performance.

2.   Purpose and Use of Information Collection

A core set of data are required annually to administer the grant programs funded under Section 330 and Health Center Program look-alikes. The UDS is the tool used for monitoring and evaluating health center performance, and for ensuring compliance with legislative mandates. The UDS yields consistent information on patient characteristics and clinical conditions which can be compared with other national and state data. These data are also essential in assuring compliance with legislative mandates, facilitating reports to Congress, reviewing program accomplishments, and reporting on the Government Performance Review Assessment (GPRA). The UDS is the mechanism used by HRSA to obtain these standardized data elements from health centers.

A key component of success of the Health Center Program has been the ability to demonstrate to payers and patients the value of care delivered to those receiving health center services. The expansion of the Health Center Program and the resulting growth in the number of health center patients and services, along with provider incentive programs and technological advances, have underscored the importance of demonstrating health centers' high quality of care to underserved populations.

The type of data requested in the UDS provides program information on the following: the total number of low income and/or uninsured people served; services utilized and diagnoses made; services offered which are distinct from other providers of primary care (e.g., enabling services); and staffing for major service categories.

In addition to program data, the UDS will collect a set of clinical measures that emphasize clinical performance and health outcomes. The set of clinical measures relate to:

- Newborn low birth weight
- Childhood immunizations
- Entry into prenatal care
- Cervical cancer screening
- Adult Hypertension (blood pressure levels)
- Adult Diabetes (HbA1c levels)
- Weight Assessment and Counseling for Children and Adolescents
- Adult Weight Screening and Follow Up
- Tobacco Use Screening and Cessation
- Asthma Pharmacological Therapy
- Coronary Artery Disease Lipid Therapy
- Ischemic Vascular Disease Aspirin or other Antithrombotic Therapy
- Colorectal Cancer Screening
- Depression Screening and Follow Up
- HIV Linkage to Care
- Sealants to First Molars

These measures support BPHC efforts to improve the program's ability to demonstrate its impact and effectiveness for patients, payers, and the American public, as well as to provide guidance for program improvement.

The measures are aligned with national quality standards for ambulatory care programs, e.g., those of the National Quality Forum (NQF), and the National Committee for Quality Assurance (NCQA), where applicable. They represent clinical care across the patient life cycle (i.e., newborn, childhood, and adult life cycles), and are indicative of the most prevalent conditions and preventive services addressed within the health center patient population. They were carefully selected through a deliberative process that included input from HRSA staff and vetting with health centers and partners.

The low birth weight and prenatal access to care measures have been reported by health centers in the UDS since 1996, and are included in measures recognized under the Children's Health Insurance Program Reauthorization Act (CHIPRA). The measures for childhood immunizations, cervical cancer screening, diabetes control, and blood pressure control have been reported by health centers in the UDS since 2008. These measures are all Meaningful Use measures. The four measures added in 2011 (Weight Assessment and Counseling for Children and Adolescents, Adult Weight Screening and Follow Up, Tobacco Use Assessment and Counseling, and Asthma Pharmacological Therapy) and the three measures added in 2012 (Coronary Artery Disease Lipid Therapy, Ischemic Vascular Disease Aspirin or other Antithrombotic Therapy, Colorectal Cancer Screening) also are Meaningful Use measures developed by national standard setting organizations. Introduced in UDS 2014, depression screening and follow up is endorsed by the

HHS Measures Policy Council and aligned with MU and NQF, while HIV linkage to care supports an HHS-wide action plan from the President's National HIV/AIDS strategy (NHAS). Dental sealants to first molars in children, proposed in 2015, is also in alignment with the NQF.

The program data and the clinical measures are used to track health center performance and monitor use of grant funds. They also will result in HRSA's ability to make accurate statements about the Health Center Program through performance measurement, as well as provide statistics related to underserved populations served within the health center setting.

As required by the Government Performance and Results Act (GPRA), BPHC has developed annual program goals and objectives and related performance indicators. Examples of GPRA indicators that the UDS addresses are: services provided to low income individuals, services provided to minority individuals, and percent of low birth weight births to health center patients. The UDS provides data for these and other performance indicators.

The UDS provides uniformly defined data for HRSA's Health Center Program using standard formats and definitions. In addition, it yields consistent information on patient characteristics and clinical conditions that can be compared with other national and state data.

The UDS consists of two separate components. The first component is the *Universal Report*, which is completed by all health centers. This report provides data on services, staffing, and financing across the programs included in the UDS. The second component is the *Grant Report*, which provides information on the characteristics of users whose services fall within the scope of a project funded under a particular grant. Each Grant Report includes a subset of tables which employ the same formats and definitions as the Universal Report.

Grantees that receive only one BPHC grant are required to complete only the Universal Report. Multiple-award grantees complete a Universal Report for the combined projects and a separate grant report for each Homeless, Migrant or Public Housing program grant. Look-alikes are currently only required to submit a Universal Report.

3.   Use of Improved Information Technology and Burden Reduction

Advancements in Electronic Health Record (EHR) technology have been proceeding at a rapid pace. In an effort to improve quality, safety and efficiency of care, EHR incentive programs provide a financial reward to eligible providers practicing in health centers. EHRs can help health centers achieve larger quality and efficiency goals, and the use of EHR can also streamline and simplify health center reporting to UDS measures. Once data are extracted from an EHR, they can be readily entered into the Electronic Handbook (EHB), bypassing the need for manual chart reviews and random sampling. The Electronic Handbook is the mechanism for health center reporting.

UDS reporting is completed by health centers using a web based data collection system which is completely integrated with HRSA Electronic Handbooks (EHBs). HRSA EHBs provide authentication and authorization services to all HRSA customers, and integration with that

system means that the applicants or health centers do not have to remember multiple usernames and passwords.

Respondents submit UDS data using standard web browsers through a Section 508 compliant user interface. The system provides electronic UDS data tables that clearly communicate what is required and guide the respondents in completing their UDS reporting requirement. Usability features such as those that pre-fill data from prior year grant applications based on business rules prevent redundant data entry while other features such as calendar controls to enter date speed up the data entry process. Respondents are able to work on the forms in part, save them online and return to complete them later. The approach allows applicants to distribute the data entry burden amongst multiple users if required. Business rules that check for quantitative and qualitative edit checks are applied to ensure that the data submitted meets the legislative and programmatic requirements. Respondents are provided with a summary of what is complete and what is incomplete along with links to jump to the appropriate sections to correct the identified incomplete parts. In addition, BPHC has a toll free hot line to address questions and provide assistance, including EHB concerns and constraints. The BPHC Help Desk is at bphchelpline@hrsa.gov or 877-974-2742, Monday through Friday (except federal holidays) 8:30 AM to 5:30 PM (ET).

4.   Efforts to Identify Duplication and Use of Similar Information

HRSA explored alternative sources for the cost information and found that because of differences in coverage and definitions, there are no other existing sources that could be used for grant monitoring and administration.

5.   Impact on Small Businesses or Other Small Entities

Every effort has been made to ensure that the UDS contains the minimum amount of data necessary to meet legislated monitoring and reporting requirements. Duplicative reporting has been eliminated. The UDS builds on data currently collected and maintained by health centers for internal administrative and clinical needs. As such, the UDS imposes few additional data collection demands on its health centers beyond what they already collect for internal purposes.

6.   Consequences if Information Were Collected Less Frequently

Grant dollars are awarded annually; therefore, the UDS data are required annually in order to monitor program performance and administer program funds. For look-alikes, the UDS data are used to monitor program performance and for designation and recertification decisions.

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

The request fully complies with the regulation.

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

8A. The notice required by 5 CFR 1320.8(d) was published in the *Federal Register* on August 8, 2014, Vol. 79, No. 153, page 46443. No public comments were received in response to this

notice.

8B. Request for consultation was made in August 2014. Comments from the following health centers are summarized below.

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Summary of Comments:
- UDS reporting format and instructions are satisfactory, however, release of UDS manual is requested earlier in the calendar year.

- Clinical measures should be aligned as much as possible with other requirements, such as Healthy People 2020, Patient Centered Medical Home/ National Committee for Quality Assurance (NCQA), The Joint Commission (JCAHO), Meaningful Use, Centers for Medicare & Medicaid Services Accountable Care Organizations (CMS ACO), Healthcare Effectiveness Data and Information Set (HEDIS), etc. to decrease reporting burden.
- Retrieving data for clinical measures where patients are referred out (e.g. colorectal cancer screening, cervical cancer screening, prenatal care, low birth weight) for care is challenging. Manual chart audits are necessary.
- Patients with insurance do not report income/family size, causing high numbers of unreported/unknowns.
- EHRs must be customized to accommodate new measures and extra hours are needed to compensate for a lack of editing and data cleaning capability in EHRs.
- Frequency of data collection is satisfactory. It would be very difficult and time intensive to report more than once a year.
- Some data elements are challenging and time consuming to collect. (e.g. calculating patients' age as of June 30th and not at the end of the reporting period, collecting zip codes by insurance source.)
- UDS data should be collected throughout the year in quarterly data reports, similar to American Recovery and Reinvestment Act (ARRA) reporting and Outreach and Enrollment reports. UDS should coincide with routine monthly reporting & oversight that health centers do internally on utilization, patient demographics, quality improvement outcomes and financial health.
- HRSA provides all the tools necessary to meet the reporting deliverables.

To address these comments, HRSA will continue to assess and monitor measures to align with measurement bodies, such as Healthy People 2020 and the National Quality Forum (NQF). HRSA will also convene a UDS workgroup to discuss challenges to UDS reporting and long term solutions to reporting.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

No patient/user level information is reported. Only aggregate data are collected. The UDS does not involve the reporting of personally identifiable information about individuals. The UDS specifies the reporting of aggregate data on patients and the services they receive, in addition to descriptive information about each health center and its operations and financial systems.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature. All information is reported in an aggregate format. Individuals cannot be identified based on these aggregate totals. Health centers leave blank any cells where the total is less than five.

12. Estimates of Annualized Hour and Cost Burden

12A. Estimated annualized burden hours is as follows:

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Universal Report	1,302	1	170	221,340
Grant Report	499	1	22	10,978
Total	1,302			232,318

Basis for the estimates:

The UDS includes two components:
- The **Universal Report** is completed by all grantees and look-alikes. It consists of all 10 tables captured in UDS reporting. This report provides data on services, staffing, and financing **across all programs**. The Universal Report is the source of unduplicated data on BPHC programs.
- The **Grant Reports** are completed by a sub-set of grantees **who receive multiple BPHC grants**. It consists of Tables 3A, 3B, 4, 5, 6A. These reports cover all or part of the elements of five of the Universal Report tables. They provide comparable data for that portion of their program that falls within the scope of a project **funded under a particular grant.** Separate Grant Reports are required for the Migrant Health Center, Homeless Health Care, and Public Housing Primary Care grantees _unless_ a grantee is funded under one and only one of these programs. No Grant Report is submitted for the portion of multi-funded grantee's activities supported by the Community Health Center grant.

Estimates of burden for the proposed UDS are based on data collection costs for the current UDS, adjusted by a burden estimate due to the collection of patients dually eligible for Medicare and Medicaid and reduction of the number of HbA1c categories reported in the diabetes clinical measure. The average burden per response was determined after consultation with a sample of eight potential respondent health centers. The burden per respondent varies across health centers. This burden variation is tied predominantly to the type of data system(s) used and whether or not the health center has an Electronic Health Record (EHR). While nearly all health centers use an automated system to generate the required reports, systems vary in their ease of use and flexibility. Some health centers have hierarchically-structured systems requiring time-consuming processes for retrieving data in required formats. Others have relational databases that can easily accommodate the specifications. The majority of health centers, however, are expected to experience a level of burden near the averages cited.

12B. Estimates of annualized cost to respondents is as follows:

Form name	Type of respondent	Total burden hours	Hourly wage rate	Total respondent costs
Universal report	Medical records/ health IT technician	221,340	$18	$ 3,984,120
Grant report	Medical records/	10,978	$18	$197,604

	health IT technician			

Basis for the estimates:

The data reports for Table 3A, 3B, 4, 5, 5A, 6A, 8, and parts of Tables 7 and 9D and 9E are generated automatically via Practice Management Information Systems and data reports for Table 6B and Part of 7 require a systematic sample chart audit, so the work can be performed by a mid-level staff person, such as a Medical Records and Health Information Technician, with an average wage rate of $18 per hour. (Wage rate was found on the Department of Labor website http://www.bls.gov/oes/current/oes292071.htm). The additional questions about EHR capabilities and national quality recognition can also be answered by a Medical Records and Health Information Technician with an average wage rate of $18 per hour.

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

Estimates of other total annual costs is as follows:

Activity	Type of respondent	Number of respondents	Total hours	Hourly wage rate	Total respondent cost
Data abstraction	Medical records/ health IT technician	1,302	3	18	$70,308

Activity	Average cost per respondent	Number of respondents	Total respondent cost
Programming	$1,000	1,302	$1,302,000

Basis for the estimates:

There are no capital or startup costs associated with identifying patients that are dually eligible for Medicare and Medicaid and reducing the number of HbA1c categories reported in the existing diabetes clinical measure. There is also no additional cost associated with the operation, maintenance, and purchase of reporting services. Health centers currently use their automated data systems to capture and maintain data that are reported in the UDS and for reporting to other funding sources. Medicare and Medicaid dually eligible patient data are already collected and captured for billing purposes in Practice Management Systems. Diabetes HbA1c data is also already collected and captured in health center EHRs.

It is expected that health centers will experience cost "economies" from reporting measures that are consistent with those currently endorsed by national standard setting organizations and are Meaningful Use measures. Furthermore, upon vetting with our health centers and partners, it was found that health centers already collect and report such measures to payors and other organizations.

Since this is the first reporting year for sealants on first molars, however, it is anticipated that

health centers will require additional processing time to develop reporting methods. To effectively report on the new measure, health centers are expected to utilize their existing clinical data sources – paper-based charts, electronic health records or a combination of data sources. Therefore, during the initial reporting year there will be health centers that will incur costs in the form of additional staff time. It is estimated that additional costs related to data abstraction from paper charts or EHR systems will amount to approximately $70,308 (1,302 health centers x 3 hours x $18/hour).

Health centers will also incur programming or re-programming costs for generating the data in the required format. These costs are estimated to average $1,000 per center for generating the new measure for a total of $1,302,000 ($1,000 x 1,302 health centers).

HRSA anticipates reducing the average time for a health center to report the UDS data by offering technical assistance, in-person training, telephone helpline, email box, and live and archived web-based trainings.

14. Estimated Cost to the Federal Government

The estimated annual contract cost to the federal government for technical assistance, training and data reporting support, data processing, editing, and verification is $1,300,000. In addition, costs include one FTE at 50% time at a GS 13 level, Step 1 for $45,000. Total estimated annual costs to the government are $1,345,000.

15. Explanation for Program Changes or Adjustments

This request is for 232,318 hours. This change is due to a revision in the burden estimate for the Universal and Grant report after consultation with a sample of eight potential respondent health centers. The increase in burden is attributable to the collection of patients dually eligible for Medicare and Medicaid and sealants on first molars, the reduction in the number of HbA1c categories reported in the diabetes clinical measure, hours attributable to the existing UDS data collection, and an increase of 186 respondents completing the Universal or Grant report.

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

The health centers are required to submit the reports within 90 days after the end of the calendar year. No statistical analyses are planned; summary descriptive reports from the tables will be prepared and published within 9 months after the end of the calendar year.

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

The OMB number and expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.