Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Ouided Rouabhi, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G221, Silver Spring, MD 20993–0002, 240–402–2672; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

Consistent with the goals of the Breakthrough Devices Program, FDA is proposing select updates to the Breakthrough Devices Program guidance that clarify how the program may be applicable to certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions in populations impacted by health and/or healthcare disparities. The Breakthrough Devices Program may expedite the availability of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions in populations impacted by health and/or healthcare disparities, thereby promoting and advancing health equity. Additionally, FDA is proposing updates, consistent with our obligations under the SUPPORT Act (Food, Drug, and Cosmetic Act section 515B (21 U.S.C. 360e-3)), to clarify that the Breakthrough Devices Program may be available to certain nonaddictive medical products to treat pain or addiction.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Healthcare.'' 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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the internet.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, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Select Updates for the Breakthrough Devices Program Guidance: Reducing Disparities in Health and Healthcare'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1833–R1 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. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756

Dated: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22878 Filed 10–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0915–0193—Revision]

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

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

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 must be received no later than December 20, 2022.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 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 the HRSA OMB PRA Officer, Samantha Miller, at (301) 443–1984.

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

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 12,000 service delivery sites that provide primary health care to more than 30 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 [1] for annual reporting by Health Center Program awardees (those funded under section 330 of the PHS Act), Health Center Program look-alikes, and Nurse Education, Practice, Quality and Retention [2] Program awardees (specifically those funded under the practice priority areas of section 831(b) of the PHS Act). Look-alikes do not routinely receive federal funding under section 330 of the PHS Act, but meet the Health Center Program requirements for designation under the program (42 U.S.C. 1395x(aa)(4)(A)(ii) and 42 U.S.C. 1396d(l)(2)(B)(ii)).

Need and Proposed Use of the Information: UDS data collection updates must be completed in a timely manner for health centers to fulfill Health Center Program requirements. Approval of these changes is needed by February 1, 2023, to implement the changes in the data collection system and to provide adequate information on UDS reporting guidance to health centers, partners, and key stakeholders. HRSA plans to make the following updates for the performance year 2023 UDS data collection:

- *Table 3B (Demographic Characteristics),* will be updated to include additional subpopulations selection options to better reflect the diversity of patients served by health centers. Race/ethnicity categories will be updated to align with HHS data standards.[3] In accordance with Section 4302 within the Office of the Assistant Secretary for Planning and Evaluation [4] *Implementation Guidance on Data Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status,* the UDS will be updated to include subpopulations categories for Asian, Native Hawaiian, Other Pacific Islanders, as well as a broader selection for Hispanic ethnicity. The 2011 HHS race and ethnicity categories maintains alignment with the 1997 OMB [5] minimum categories for race and ethnicity and allow for better understanding of the cultural diversity of patients served by health centers.
- *Table 5 (Staffing and Utilization),* will be updated to include four distinct lines for reporting Pharmacy Personnel categorized by Pharmacists, Clinical Pharmacist, Pharmacy Technicians, and Other Pharmacy Personnel. Health center personnel are critical to the functioning of health centers, collecting inclusive information about the health center workforce, and will allow HRSA to better understand workforce composition as well as improve the ability to articulate the role that pharmacy personnel play in an integrated primary care.
- *Table 6A (Selected Diagnoses and Services Rendered),* will be updated to include a diagnostic measure representing long COVID. This measure is labeled *Post COVID–19 condition, unspecified,* within the Selected Infectious and Parasitic Diseases grouping of measures. With this measure, health centers are able to report both number of patients with this diagnosis as well as the number of patient visits related to the diagnosis.[6] The Centers for Disease Control and Prevention classifies long COVID, also known as post-COVID, conditions as a wide range of new, returning, or ongoing health problems people can experience four or more weeks after first being infected with the virus that causes COVID–19.[7] Data on this measure will lead to better understanding the impact of COVID–19 post-acute infection on health center patients.
- *Table 6A (Selected Diagnoses and Services Rendered),* will be updated to include a measure that tracks the number of patients who receive pediatric developmental screening and evaluation services. The 2023 UDS will include developmental screening, behavioral screening/testing, and administrative assessment International Classification of Diseases diagnostic and Current Procedural Terminology billing codes for use to track the changes in the number of children who receive developmental screening and evaluation services. Early childhood is a critical period for physical, cognitive, and social development, laying the foundation for life-long health and well-being.[8] Children who experience poverty, particularly during early life, are at risk of adverse health and developmental outcomes.
- *Table 6B* (*Quality of Care Measures*), and *Table 7* (*Health Outcomes and Disparities*), collected UDS clinical quality measures [9] (CQMs) where applicable. Collected UDS CQMs will be updated in alignment with specifications of the issued performance year 2023 electronic-specified clinical quality measures, released by the Centers for Medicare and Medicaid Services for use by eligible providers. 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.
- *Appendix D (Health Center Health Information Technology* {*HIT*} *Capabilities Form),* will be updated with a question asking health centers to provide the total number of patients that were screened for social risk factors, using a standardized screener, during the calendar year. This question provides a more accurate view of the impact of social risk on the health center patient population and continues to reinforce Social Determinants of Health as a priority area intrinsically linked with health equity.

[1] *https://www.cms.gov/files/document/sgm-clearinghouse-uds.pdf.*

[2] *https://www.hrsa.gov/grants/find-funding/hrsa-20-012.*

[3] *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0.*

[4] *https://aspe.hhs.gov/reports/hhs-implementation-guidance-data-collection-standards-race-ethnicity-sex-primary-language-disability-0#:~:text=Section%204302%20requires%20the%20Secretary,all%20national%20population%20health%20surveys.*

[5] *https://obamawhitehouse.archives.gov/omb/fedreg_1997standards.*

[6] *https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html.*

[7] *https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html.*

[8] *https://www.hrsa.gov/grants/find-funding/hrsa-22-091.*

[9] *https://www.cms.gov/regulations-and-guidance/legislation/ehrincentiveprograms/downloads/guidetocqms_remediated_2011.pdf.*

- Beginning with the *2023 UDS,* health centers will be able to submit 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+ Patent Level Reporting leverages a methodological shift in the process by which health centers submit their annual UDS report while maintaining historic UDS measures. High-quality accessible data are critical to strategically meeting the needs of patients and identifying opportunities for clinical process improvement. The growth in health information technology coupled with the increased adoption of electronic health records has transformed patient care delivery and underscored the need for secure and rapid exchange of health data between disparate systems. Health Level Seven International [10] developed Fast Healthcare Interoperability Resources [11] (FHIR) to standardize the electronic exchange of patient data across systems. FHIR, which is the current gold standard, has the flexibility to support a variety of user needs and enhances interoperability by transmitting health data rapidly and more securely than ever before. It is important for the collection of UDS data to align with interoperability standards and reporting requirements across HHS and the healthcare industry. Leveraging FHIR to collect UDS patient-level data will improve data granularity, allow for the development of robust patient management programs, and improve equitable access to 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: Likely respondents will include Health Center Program award recipients, Health Center Program look-alikes, and Nurse Education, Practice, Quality and Retention Program awardees funded under the practice priority areas of section 831(b) of the PHS Act.

Burden Statement: Burden includes 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 use technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, disclosing and providing information. It also accounts for time to train personnel, respond to a collection of information, search data sources, complete and review the collection of information, and transmit or otherwise disclose the information. It will also include testing information necessary to support the UDS Test Cooperative (UTC). No more than three tests will be conducted each calendar year and no more than one hundred health centers will participate in one test. Participation is voluntary and will not affect their funding status. This sample size is sufficient to conduct a technical test and determine if the innovation should be scaled across the UDS. The total annual burden hours estimated for this ICR are summarized in the forthcoming table.

Form name	Estimated number of respondents	Estimated number of responses per respondent	Average burden per response (in hours)	Estimated total burden hours
Universal Report	Total: 1,505 H80s: 1,370 LALs: 117 BHW: 18	1.00	238	358,190
Grant Report	Total: 438 438 Health Centers submitted one or more Grant Reports. 1: 346 2: 80 3: 12	1.24	30	16,294
UTC Tests	35	3.00	8	840
Total	1,978	5.24		375,324

HRSA specifically requests comments on: (1) the necessity and feasibility 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. 2022–22867 Filed 10–20–22; 8:45 am]

BILLING CODE 4165–15–P

[10] *https://www.hl7.org/.*

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

[OMB No. 0906–0043–Extension]

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Evidence-Based Telehealth Network Program Measures

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 December 20, 2022.