expected to produce the same clinical result as the reference product in any given patient and, if the biological product is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between the use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch (section 351(k)(4) of the PHS Act). Interchangeable biosimilar products may be substituted for the reference product without the intervention of the prescribing healthcare provider (section 351(i)(3) of the PHS Act). Decisions regarding pharmacy-level substitution are subject to State pharmacy law.

The guidance discusses considerations for presenting data and information about reference products or biosimilar products, including interchangeable biosimilar products, in promotional communications to help ensure that they are accurate, truthful, and non-misleading. The guidance includes information about general requirements for the content of FDA-regulated promotional communications that apply to reference products and biosimilar products and includes more specific considerations for developing these promotional communications for reference products and biosimilar products, such as:

- Identifying reference products and biosimilar products
- Presenting information from the studies conducted to support licensure of the reference product when the information is included in the FDA-approved labeling of both the reference product and the biosimilar product
- Presenting data or information for a biosimilar product related to the safety or effectiveness of the biosimilar product that is not included in the FDA-approved labeling but is consistent with the FDA-approved labeling for that product
- Comparing a biosimilar product and its reference product
- Submitting promotional communications to FDA

The guidance also provides examples to illustrate some of the considerations outlined in the guidance.

This guidance finalizes the revised draft guidance of the same title issued on April 25, 2024 (89 FR 31757) (2024 draft guidance). FDA considered comments received on the 2024 draft guidance as the guidance was finalized.

Changes from the 2024 draft guidance to the final guidance include:

- Clarification that the recommendations in the guidance apply regardless of the medium of communication (*e.g.,* paper, digital)
- Further discussion related to the considerations that firms should take into account when comparing biosimilar products and reference products
- Editorial changes for consistency, readability, and clarity

In conjunction with the enactment of the Biosimilar User Fee Amendments of 2022 (BsUFA III), FDA agreed to work toward publishing a final guidance on promotional labeling and advertising considerations for interchangeable biosimilar products within 18 months after the close of the public comment period on the draft guidance, as described in the document titled ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027.''

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 ''Promotional Labeling and Advertising Considerations for Prescription Biological Reference Products, Biosimilar Products, and Interchangeable Biosimilar Products: Questions and Answers.'' 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.

FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

II. Paperwork Reduction Act of 1995

While this guidance contains no 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 21 CFR part 314, Form FDA 2253 (Transmittal of Advertisements and Promotional Labeling for Drugs and Biologics for Human Use), and the guidance for industry entitled ''Providing Regulatory Submissions in Electronic and Non-Electronic Format: Promotional Labeling and Advertising Materials for Human Prescription Drugs'' have been approved under OMB control number 0910–0001. The collections of information in 21 CFR 601.12 have been approved under OMB control number 0910–0338. The collections of information in 21 CFR 202.1 and in the guidance for industry entitled ''Medical Product Communications That Are Consistent With the Food and Drug Administration Required Labeling: Questions and Answers'' have been approved under OMB control number 0910–0686. The collections of information in 21 CFR part 11 relating to electronic records and signatures have been approved under OMB control number 0910–0303. The collections of information relating to the submission of biosimilar and interchangeable product applications under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) have been approved under OMB control number 0910–0718.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov*.

Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–22427 Filed 12–9–25; 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; 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.

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 February 9, 2026.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 13N82, 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 Samantha Miller, 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 funded health centers operate more than 16,200 service delivery sites that provide primary health care to more than 32 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 non-institutional settings to demonstrate methods for improving 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 support program compliance, inform quality improvement initiatives, guide the delivery of technical assistance, and shape federal health program decisions. To keep this instrument relevant and responsive to the Health Center Program's needs and Administration priorities, periodic updates are essential. HRSA proposes to make the following updates for the performance year 2026 UDS data collection:

Table 4: Selected Patient Characteristics

Removal

- Managed Care Utilization—UDS measures associated with managed care member months, *Capitated Member Months, Fee-for-Service Member Months,* and *Total Member Months* (Lines 13a–13c) will be removed to reduce the reporting burden, given variations in payer structures and payment arrangements across health centers.

Table 6A: Selected Diagnoses and Services Rendered

Removals

- *Various Clinical Measures*—Clinical measures associated with various diagnoses and selected services rendered are being removed from Table 6A to streamline reporting, reduce burden, and eliminate potential redundancies where similar information is captured elsewhere in the UDS. These updates align with the Administration and HRSA's priorities to simplify data collection and focus reporting on measures that provide the greatest programmatic value. The specific measures proposed for removal are indicated below:
- Novel coronavirus (SARS–CoV–2) disease (Line 4c)
- Long COVID (Line 4d)
- Respiratory conditions related to COVID–19 (Line 6a)
- Abnormal breast cancer findings, female (Line 7)
- Abnormal cervical findings (Line 8)
- Contact dermatitis and other eczema (Line 12)
- Novel coronavirus (SARS–CoV–2) diagnostic test (Line 21c)
- Novel coronavirus (SARS–COV–2) antibody test (Line 21d)
- Mammogram (Line 22)
- Pap test (Line 23)
- Sealants (Line 30)
- Oral surgery (extractions and other surgical procedures) (Line 33)
- Rehabilitative services (Endo, Perio, Prostho, Ortho) (Line 34)

Additions

- *Type I Diabetes*—A new measure is being added as line 9a to identify the number of patients with Type 1 Diabetes. This addition will help address key data gaps and improve HRSA's understanding of the distinct care and resource needs of patients with Type 1 Diabetes.
- *Intellectual and Developmental Disabilities*—A new measure is being added as line 20g to capture the number of patients with intellectual and developmental disabilities. Available data indicate that this population may experience lower rates of access to preventive and chronic care, including fewer screenings, lower dental care utilization, and higher rates of undiagnosed or unmanaged conditions. Capturing this information will improve understanding of the prevalence of persons with intellectual and developmental disabilities in the Health Center Program and support efforts to enhance health care access and quality of care for individuals requiring complex coordinated services.
- *Autism Spectrum Disorder Screening*—A new measure is being added as line 26g to capture the number of patients screened for autism spectrum disorder. This measure, in alignment with Administration priorities, will help assess the extent to which health centers are implementing recommended developmental screening practices and connecting children and families to needed support services.
- *Patient Support Services*—Four new measures are being added as lines 35–38 to capture the number of patients receiving case management, eligibility assistance, transportation, and language assistance services to better understand the range of non-clinical services that facilitate access to care and contribute to improved patient outcomes.
- *Health-Related Needs*—Four new measures are being added as lines 39–42, transitioning from Appendix D to the UDS core tables, to identify the number of patients who are screened for, and who receive, services addressing health-related needs. These or similar measures are now being elevated to the core reporting set to support standardized data collection. Integrating these measures within the core tables will enhance the ability to monitor how health centers identify and address patients' access to and utilization of services.

Table 6B: Quality of Care Measures and Table 7: Health Outcomes

Updates

• *Clinical Quality Measures*—Tables 6B and 7 collect UDS clinical quality measures, and where applicable, clinical quality measures will be updated in alignment with specifications of the issued performance year 2026 electronic clinical quality measures. These specifications were released by the Centers for Medicare & Medicaid Services on May 8, 2025, for use by eligible providers. Aligning clinical performance measures across national programs promotes data standardization, quality, and transparency, and decreases the reporting burden for providers and organizations participating in multiple federal programs.

Table 8A: Financial Costs

Removals

• *Allocation of Facility and Non-Clinical Support Services*—Allocation of Facility and Non-Clinical Support Services, Column b, and the requirement to report overhead costs on Table 8A will be removed.

• *Enabling Services*—Details for Cost of Enabling Services, Lines 11a, 11b, 11c, 11d, 11e, 11f, and 11h will be removed. These costs will be consolidated into a single line to reflect all Patient Support Services costs (previously known as Enabling Services).

• *Donations*—Line 18, Value of Donated Facilities, Services, and Supplies (specify ____), will be removed.

These updates are being made to reduce the reporting burden, aligning with the Administration and HRSA's priorities and Health Center Program stakeholder feedback.

Table 9D: Patient Service Revenue

Removals

• *Retroactive Settlements, Receipts, and Paybacks*—measures associated with Columns c1—c4 for classification of collections will be removed:

- Collection of Reconciliation/ Wraparound Current Year (c1)
- Collection of Reconciliation/ Wraparound Previous Years (c2)
- Collection of Other Payments: Pay for Performance, Risk Pools, etc. (c3)
- Penalty/Payback (c4)

• *Payer Category*—Managed care lines have been consolidated as part of total payor revenue. *Total Medicaid* (Line 3), *Total Medicare* (Line 6), *Total Other Public* (specify) (Line 9), and *Total Private* (Line 12) will be reported, and the following lines will be removed as a result:

- Medicaid Non-Managed Care (Line 1)
- Medicaid Managed Care (capitated) (Line 2a)
- Medicaid managed Care (fee-for-service) (Line 2b)
- Medicare Non-Managed Care (Line 4)
- Medicare Managed Care (capitated) (Line 5a)
- Medicare Managed Care (fee-for service) (Line 5b)
- Other Public, including Non-Medicaid Children's Health Insurance Program (CHIP), Non-Managed Care (Line 7)
- Other Public, including Non-Medicaid CHIP, Managed Care (capitated) (Line 8a)
- Other Public, including Non-Medicaid CHIP, Managed Care (fee-for-service) (Line 8b)
- Private Non-Managed Care (Line 10)
- Private Managed Care (capitated) (Line 11a)
- Private Managed Care (fee-for-service) (Line 11b)

These updates are being made to reduce the reporting burden, aligning with the Administration and HRSA's priorities and stakeholder feedback.

Additions

• *Net Patient Services Revenue*—A new column will be added for *Net Patient Services Revenue* (charges less adjustments) (Line 16, Column g).

• *Pharmacy Net Patient Service Revenue*—A new line will be added to reflect all *Pharmacy Net Patient Service Revenue* (Line 17, Column g).

• *Third-Party Incentive Revenue*—A new line will be added for *Third-Party Incentive Revenue* (Line 18, Column g).

These updates are being made to reduce reporting burden and to better assess financials in alignment with generally accepted accounting principles.

Table 9E: Other Revenue

Removals

• *HRSA's Bureau of Primary Health Care (BPHC) Grants*—Health Center Program grant funding sources (formerly Lines 1a–1e) and other BPHC funding detail lines (formerly Lines 1o–1q) will be removed. Grants with active funding will be aggregated and reported on the *Total Health Center BPHC Grants* line (Line 1), while those no longer receiving funding will be excluded from reporting.

• *Other Federal Grants*—Other federal grant funding sources (formerly Lines 2 and 3) will be removed.

These updates are being made to align with supplemental funding being rolled into the base Health Center Program funding, as well as to remove outdated supplemental funding lines and reduce the reporting burden.

Appendix D: Health Center Information Technology (Health IT) Capabilities and Appendix E: Other Data Elements

Removals

• *Appendix D: Health IT Capabilities*—Several questions specific to Electronic Health Records implementation (Questions 1a, 1a2, 1a3, 1c, 1c1, and 10) will be removed from Appendix D.

• *Appendix D: Health IT Capabilities*—Health-related needs screening questions (Questions 11, 11a, 12, 12a, and 12b) will be removed from Appendix D.

• *Appendix E: Other Data Elements*—Appendix E will be removed, and certain data elements will be combined with Appendix D. Outreach and enrollment assists (formerly Appendix E, Question 3) will be removed (aspects will be incorporated in the Table 6A Patient Support Services addition).

These updates are being made to reduce the reporting burden, aligning with the Administration and HRSA's priorities and stakeholder feedback.

Additions

• *Appendix D: Health IT Capabilities*—Three questions on Alternative Payment Models (APM) will be added to Appendix D (Questions 17–19), to include:

- What payor arrangements do you have for value-based purchasing contracts?
- Please list the types of APMs your health center is involved in.
- What percentage of your health center's revenue during the year is tied to value-based payment contracts?

These additional data elements are being proposed to capture health centers' participation in APMs to improve understanding of the evolving payment landscape within the Health Center Program. As health centers increasingly engage in payment arrangements that emphasize value, care coordination, and outcomes rather than volume of services, collecting information on APM participation will provide valuable insight into the range and scope of these models.

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
UDS—Universal Report	Total: 1,605 H80s: 1,358 Look-Alikes: 171 Bureau of Health Workforce: 76	1.00	1,605.00	185.08	297,053.40
UDS Grant Report	Total: 419 Health Centers will submit one or more Grant Reports in 2026. 1 Grant Report: 337 2 Grant Reports: 71 3 Grant Reports: 11	1.22	511.18	20.80	10,632.54
Total	2,024.00		2,116.18		307,685.94

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. 2025–22443 Filed 12–9–25; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council on Aging.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Aging.

Date: May 12–13, 2026.

Closed: May 12, 2026, 2:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: Natcher Building, Building 45, 45 Center Drive, Bethesda, MD 20892 (In Person Meeting).

Closed: May 13, 2026, 8:00 a.m. to 9:00 a.m.

Agenda: NIA IRP Review.

Address: Natcher Building, Building 45, 45 Center Drive, Bethesda, MD 20892 (In Person Meeting).

Open: May 13, 2026, 9:00 a.m. to 12:30 p.m.

Agenda: Call to Order and Director's Status Report; Council Business; Meeting Adjourned.

Address: Natcher Building, Building 45, 45 Center Drive, Bethesda, MD 20892 (In Person Meeting).

Contact Person: Kenneth Santora, Director, Office of Extramural Activities, National Institute on Aging, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20814, (301) 496–9322, *ksantora@nih.gov.*

In the interest of security, NIH has procedures at *https://security.nih.gov/visitors/Pages/visitor-campus-access.aspx* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nia.nih.gov/about/naca,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: December 8, 2025.

Margaret Vardanian,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2025–22458 Filed 12–9–25; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[OMB Control Number 1651–0111]

Agency Information Collection Activities; Revision; Arrival and Departure Record (Form I–94) and Electronic System for Travel Authorization (ESTA)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 60-Day notice and request for comments.