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.

Title of the Collection: Ensure a Strong Public Health Supply Chain Through Streamlined Oversight and American Priorities.

Type of Collection: Extension.

Office of Management and Budget (OMB) No. 0990–0488—Administration for Strategic Preparedness and Response—Center for Industrial Base Management and Supply Chain.

Abstract

HHS, Administration for Strategic Preparedness and Response (ASPR) is seeking approval by OMB on an extension of the existing clearance (OMB Control Number: 0990–0488, Expiration Date: March 31, 2026). HHS is working with the White House and across the federal interagency to launch a multiyear implementation involving the identification and coordination of measurable activities across the United States government, state, local, tribal, and territorial (SLTT) jurisdictions, and private sector partners. Cross-sectoral engagement is the underpinning of many of the interdependent implementation activities. For example, one such activity involves information collection from SLTT partners on facility, local, and state stockpiling plans to ensure coordinated plans are in place for a future public health emergency. Potential engagements include, and are not limited to, surveys, stakeholder meetings, requests for information (RFI), town hall meetings, and workshops. With each of these different mechanisms of engagement, there is a varied frequency ranging from single engagements to regularly recurring meetings.

In 2025, the White House capacity and strengthening the public health supply chain through a series of executive actions focused on reducing foreign dependency, enhancing domestic manufacturing capacity, and improving emergency preparedness. This includes the establishment of the Strategic Active Pharmaceutical Ingredients Reserve (SAPIR), directed by HHS and managed through ASPR, to ensure a secure, domestic supply of essential drug components. The administration has also invoked Section 232 of the *Trade Expansion Act* of 1962 to assess whether reliance on imports of materials such as processed critical minerals and copper poses a national security risk, including risks to the production of pharmaceuticals and other medical countermeasures. These coordinated efforts reflect a broader federal strategy to increase the resilience, agility, and visibility of the public health supply chain in support of future emergency response operations. To support White House priorities, HHS seeks a 3-year extension to its Paperwork Reduction Act clearance and will engage with SLTT, trade groups, mixed cross-sector audiences, non-governmental organizations, manufacturers, academia, healthcare providers and facilities, and local communities.

ESTIMATED ANNUALIZED BURDEN TABLE OVER THREE YEARS

Type of respondent	Form name	Number of respondents	Number responses per respondent	Average burden per response (in hours)	Total burden hours
Private sector companies, SLTT, Trade groups and associations, NGOs, Manufacturers, distributors, Academia, Healthcare delivery providers/facilities, Public, USG Supply chain inventory holders, Biopharmaceutical industry, Biotechnology development companies, Communities, GPOs, standards development organizations, logistics, third party contractors, purchasing organizations, professional associations/societies, Mixed cross-sector audience, labor unions, workforce training providers, organizations, state and local workforce boards, and individuals who rely on wearable medical countermeasures.	Informed consent	32,800	1	0.08	2,624
	Demographics standardized questionnaire with decision logic allowing some questions to be omitted.	32,800	1	0.25	8,200
	Cognitive questionnaire	5,990	1	8	47,920
	Formative interviews and focus groups	6,600	2	4	52,800
	Town halls and public meetings	10,200	2	8	163,200
	Supply chain questionnaires	1,000	156	0.5	78,000
	Knowledge-based questionnaires	6,000	1	0.5	3,000
	Interviews and focus groups	3,000	1	1	3,000
	Instrumented information collection	160	1	0.5	80
Total Burden Hours Over Three Years					358,824

Catherine Howard,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2025–23759 Filed 12–22–25; 8:45 am]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

RIN 0955–AA13

Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care

AGENCY: Office of the Deputy Secretary and Assistant Secretary for Technology Policy (ASTP) and Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services.

ACTION: Request for information.

SUMMARY: The HHS Office of the Deputy Secretary in collaboration with ASTP/ONC has published this Request for Information (RFI) to seek broad public comment on what HHS can do to accelerate the adoption and use of AI as part of clinical care.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, by February 23, 2026.

ADDRESSES: You may submit comments, identified by ''HHS Health Sector AI RFI,'' by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *http://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology, Attention: Request for Information: HHS Health Sector AI RFI, Mary E. Switzer Building,

Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.

• *Hand Delivery or Courier:* Assistant Secretary for Technology Policy and the Office of the National Coordinator for Health Information Technology, Attention: HHS Health Sector AI RFI, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies. (Because access to the interior of the Mary E. Switzer Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the mail drop slots located in the main lobby of the building.)

Inspection of Public Comments: All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. Such information includes but is not limited to: a person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; any personal health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *http://www.regulations.gov.*

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* or the Department of Health and Human Services, Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201 (call ahead to the contact listed below to arrange for inspection).

FOR FURTHER INFORMATION CONTACT: Steven Posnack, Principal Deputy Assistant Secretary for Technology Policy, ASTP/ONC, 202–690–7151.

SUPPLEMENTARY INFORMATION:

I. Introduction

On December 4, 2025, the Department of Health and Human Services (HHS) issued the HHS Artificial Intelligence (AI) Strategy [1] in response to Office of Management and Budget (OMB) Memorandum 25–21.[2] The HHS AI Strategy represents a ''OneHHS'' approach to AI and is primarily focused on the Department's internal interests and ambitions to harness the transformative potential of AI and embed it into HHS's operations, while upholding patient privacy, civil rights, and civil liberties. Consistent with the President's artificial intelligence (AI) Action Plan,[3] recent Executive Orders [4] on AI, and Office of Management and Budget AI memoranda,[5] the Department seeks public feedback on the actions it can take to establish a forward-leaning, industry-supportive, and secure approach to accelerate the adoption and use of AI [6] as part of clinical care. In the past 12 months, HHS Divisions, including the Food and Drug Administration (FDA),[7] National Institutes of Health (NIH),[8] Centers for Medicare & Medicaid Services (CMS),[9] and ASTP/ONC [10] have sought public feedback on various aspects of AI and how it intersects with the Department's policy interests. In this RFI we seek concrete, experience-based feedback from those building, buying, evaluating, using, and receiving care from AI tools that are part of clinical care as well as from those who wish to do so but face barriers. Public feedback will inform HHS-wide use of three different approaches: regulation, reimbursement, and research & development. In general, HHS seeks feedback on ways in which these approaches can be most effectively applied to support the rapid adoption and use of AI in clinical care, to foster public trust and confidence in modern technology solutions, to reduce uncertainty that impedes AI innovation, and to align federal incentives so that AI is deployed in ways that enhance productivity, reduce burden, lower health care costs, and improve health outcomes for patients, caregivers, and communities.

II. Solicitation of Public Comments

Regulation

As the nation's principal health regulator, HHS helps shape the environment in which AI for clinical care is developed, evaluated, and deployed. HHS seeks to establish a regulatory posture on AI that is well understood, predictable, and proportionate to any risks presented to enable rapid innovation while protecting patients and the confidentiality of their identifiable health information, and maintaining public trust. We seek feedback on how current HHS regulations impact AI adoption and use for clinical care.

Reimbursement

HHS's payment policies and programs have massive effects on how health care is delivered in the United States, often times with unintended consequences. Hypothetically, if a payer is taking financial risk for the long-term health and health costs of an individual, that payer will have an inherent incentive to promote access to the highest-value interventions for patients. Under government designed and dictated fee-for-service regimes, however, coverage and reimbursement decisions are slow. Rarely does covering new innovations reduce net spending; and waste, fraud, and abuse is difficult to prevent, often times leading to massive spending bubbles on concentrated items or services that are not commensurate with the value of such products. Given the inherent flaws in legacy payment systems, we seek to ensure that the potential promises of AI innovations are not diminished through inertia and instead such payment systems are modernized to meet the needs of a changing healthcare system. We seek feedback on payment policy changes that ensure payers have the incentive and ability to promote access to high-

[1] *https://www.hhs.gov/press-room/hhs-unveils-ai-strategy-to-transform-agency-operations.html.*

[2] *https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-21-Accelerating-Federal-Use-of-AI-through-Innovation-Governance-and-Public-Trust.pdf.*

[3] *https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf.*

[4] *https://www.ai.gov/#resources-anchor.*

[5] See: *https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-21-Accelerating-Federal-Use-of-AI-through-Innovation-Governance-and-Public-Trust.pdf* and *https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-22-Driving-Efficient-Acquisition-of-Artificial-Intelligence-in-Government.pdf* and *https://www.whitehouse.gov/wp-content/uploads/2025/12/M-26-04-Increasing-Public-Trust-in-Artificial-Intelligence-Through-Unbiased-AI-Principles-1.pdf.*

[6] For purposes of this RFI, ''artificial intelligence'' is defined to be consistent with OMB Memorandum M25–21, which follows the meaning provided in Section 238(g) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019. See section 5 of M25–21 for additional detail.

[7] FDA Request for Public Comment: Measuring and Evaluating AI-enabled Medical Device Performance in the Real-World *https://www.fda.gov/medical-devices/digital-health-center-excellence/request-public-comment-measuring-and-evaluating-artificial-intelligence-enabled-medical-device.*

[8] NIH Request for Information: Inviting Comments on the NIH Artificial Intelligence Strategy *https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-117.html.*

[9] CMS Request for Information on Artificial Intelligence Technologies for Improving Health Care Outcomes and Service Delivery *https://www.cms.gov/digital-service/artificial-intelligence-demo-days.*

[10] CMS and ASTP/ONC Request for Information: Health Technology Ecosystem *https://www.federalregister.gov/documents/2025/05/16/2025-08701/request-for-information-health-technology-ecosystem.*

value AI clinical interventions, foster competition among clinical care AI tool builders, and accelerate access to and affordability of AI tools for clinical care.

Research & Development

HHS supports one of the world's largest health research ecosystems, catalyzing innovation to supplement the market. By enabling applied AI research & development, care delivery research and implementation science, as well as AI entrepreneurship in health care, we can better translate AI technologies from concept to clinical use. We seek input on ways in which HHS may invest in research & development (including public-private partnerships and cooperative research and development agreements (CRADAs)) to integrate AI in care delivery and create new, long-term market opportunities that improve the health and wellbeing of all Americans.

Specific Questions

In addition to the general requests for information above regarding AI regulation, reimbursement, and research & development, HHS seeks input on the following specific questions:

1. What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?

2. What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.

3. For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (*e.g.,* relating to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?

4. For non-medical devices, what are the most promising AI evaluation methods (pre- and post-deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care? Should HHS further support these processes? If so, which mechanisms would be most impactful (*e.g.,* contracts, grants, cooperative agreements, and/or prize competitions)?

5. How can HHS best support private sector activities (*e.g.,* accreditation, certification, industry-driven testing, and credentialing) to promote innovative and effective AI use in clinical care?

6. Where have AI tools deployed in clinical care met or exceeded performance and cost expectations and where have they fallen short? What kinds of novel AI tools would have the greatest potential to improve health care outcomes, give new insights on quality, and help reduce costs?

7. Which role(s), decision maker(s), or governing bodies within health care organizations have the most influence on the adoption of AI for clinical care? What are the primary administrative hurdles to the adoption of AI in clinical care?

8. Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care? Please consider specific data types, data standards, and benchmarking tools.

9. What challenges within health care do patients and caregivers wish to see addressed by the adoption and use of AI in clinical care? Equally, what concerns do patients and caregivers have related to the adoption and use of AI in clinical care?

10. Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?

a. Are there published findings about the impact of adopted AI tools and their use clinical care?

b. How does the literature approach the costs, benefits, and transfers of using AI as part of clinical care?

III. Paperwork Reduction Act

In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), and OMB guidance, this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

IV. Response to Comments

Due to the large number of public comments that we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this request for information.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2025–23641 Filed 12–19–25; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Loan Repayment Programs (LRP), (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the NIH will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Matthew Lockhart, Director, Division of Loan Repayment (DLR), National Institutes of Health, 6705 Rockledge Dr, (MSC 7963), Bethesda, Maryland 20892–7963 or email your request, including your address to: *matthew.lockhart@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3)