Compliance Plan for

OMB Memorandum M-25-21

This Compliance Plan was issued on September 30, 2025 by HHS Acting Chief Artificial Intelligence Officer Clark Minor consistent with OMB Memorandum M-25-21.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Introduction

Following recent advances in Artificial Intelligence (AI) capabilities, in January 2025, President Trump issued Executive Order (EO) 14179[1] on Removing Barriers to American Leadership in Artificial Intelligence, which directs federal agencies to dismantle barriers to U.S. AI innovation and to sustain U.S. AI leadership. Subsequently, on April 3, 2025, the White House Office of Management and Budget (OMB) released two memoranda delineating implementation of this EO for federal agencies: Memorandum M-25-21 on Accelerating Federal Use of AI through Innovation, Governance, and Public Trust[2] and Memorandum M-25-22 on Driving Efficient Acquisition of Artificial Intelligence in Government.[3] These Memos focus U.S. AI policy towards a "forward-leaning, pro-innovation, and pro-competition mindset" and direct agencies to leverage AI to be "more agile, cost-effective, and efficient."

To address these directives, HHS's Compliance Plan mirrors the main pillars of M-25-21:

- Driving AI innovation
- Improving AI Governance
- Fostering Public Trust in Federal Use of AI

Under the leadership of Secretary Kennedy and Deputy Secretary O'Neill, the HHS Chief AI Officer (CAIO) will coordinate across all HHS Divisions (e.g., the Administration for Children and Families (ACF), the Centers for Disease Control and Prevention (CDC), the Centers for Medicare & Medicaid Services (CMS), the Food and Drug Administration (FDA), Indian Health Services (IHS), the National Institutes of Health (NIH), and many others) to implement the requirements and recommendations set forth in M-25-21, Section 3(b)(ii). In addition, the recently released HHS AI Strategy elaborates on these pillars and further specifies strategic goals, and potential metrics to track implementation progress.

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[1] Removing Barriers to American Leadership in Artificial Intelligence – The White House
https://www.whitehouse.gov/presidential-actions/2025/01/removing-barriers-to-american-leadership-in-artificial-intelligence/
[2] M-25-21 Accelerating Federal Use of AI through Innovation Governance and Public Trust
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] M-25-22 Driving Efficient Acquisition of Artificial Intelligence in Government
https://www.whitehouse.gov/wp-content/uploads/2025/02/M-25-22-Driving-Efficient-Acquisition-of-Artificial-Intelligence-in-Government.pdf

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Scope

In line with the Administration's AI Action Plan[4], Executive Orders, and implementation guidance, HHS is committed to removing barriers to American leadership in AI. The HHS Compliance Plan establishes principles, guidelines, and policies to drive AI innovation. By leveraging the best of American AI, HHS will empower its workforce and guide the sector to further the Department's mission to, "enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services."

Nothing in this Plan should be construed to conflict with or supersede Federal law or regulations.

Driving AI Innovation

Removing Barriers to the Use of AI

Led by the CAIO, HHS will routinely assess and identify barriers to the use of AI and determine techniques and approaches to minimize these barriers. To date, HHS has identified opportunities across several domains, including:

- Funding and procurement;
- Information technology (IT) infrastructure;
- Product development;
- Operations and maintenance;
- Data management and sharing;
- Cybersecurity; and
- Talent and workforce development.

HHS is taking a multi-pronged, multi-stage approach to these opportunities. Efforts include:
- Defining and distributing best practices, Standard Operating Procedures (SOPs), AI-related training, and other methods of promoting transparency and efficiency for use of AI;
- Accelerating the Authority to Operate (ATO) process for AI products to speed up implementation of AI technologies while adhering to risk management guidance and principles, and to improve access to software, open-source libraries, and deployment and monitoring capabilities necessary to rapidly develop, test, and maintain AI applications; and
- Implementing internal policies and strategic direction that encourage piloting, maturing and scaling use cases.

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[4] America's AI Action Plan https://www.whitehouse.gov/wp-content/uploads/2025/07/Americas-AI-Action-Plan.pdf

Sharing and Reuse

M-25-21 states, "agencies must proactively share across the Federal Government their custom-developed code-including models and model weights-whether agency developed or procured, for AI applications in active use." In coordination with the Office of the Chief Information Officer (OCIO) and relevant program offices across HHS Divisions, the Acting CAIO will ensure Divisions proactively share any custom-developed code – including models and model weights – for AI applications in active use covered by the SHARE-IT Act.[5] Aligned with the SHARE-IT Act and the HHS Living Open Data Plan, HHS will operate with an "open by default" mindset by releasing and maintaining custom-developed code as open-source software in a public repository when possible and in accordance with the law. Through a central OneHHS vision laid out in the recently published HHS AI Strategy, grassroots efforts across Divisions, and where appropriate, HHS will establish a culture of sharing AI code, models, and data assets to empower discovery and innovation across the Department and industry.

AI Talent

HHS seeks to attract and empower the best and the brightest in health care and human services delivery. In collaboration with the HHS Chief Human Capital Officer, the HHS Acting CAIO will utilize all tools available to recruit and to retain AI talent. First, HHS will instruct an HHS AI talent lead to identify critical functional gaps and opportunities across the Department. Then, by creating roles for subject matter experts – from data scientists, to AI engineers, to administrative staff championing AI use cases in their daily work – HHS will attract optimal candidates, including from within the Department. The Department is committed to hiring and retaining individuals who have operational experience in designing, deploying, and scaling AI systems in high-impact environments.

Additionally, HHS will continue to provide employees with training programs and resources to upskill with AI. Annual trainings are already available government-wide through OMB and GSA, and several Divisions have developed bespoke training for professionals within the Department to strengthen their technical skills. By addressing needs at all levels, employees will learn skills from the basics of prompt engineering and retrieval augmented generation to training and refining models.

To complement these trainings, HHS will create platforms for knowledge sharing and best practices, including webinars, forums, and collaborative online spaces. Talent exchange programs will be considered, allowing employees to work on temporary assignments in other agencies to gain diverse experience and insights. Finally, the Department may pursue the use of AI competitions with other agencies and outside of government to foster innovation using AI in health care and human services delivery.

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[5] H.R.9566 - 118th Congress (2023-2024): SHARE IT Act https://www.congress.gov/bill/118th-congress/house-bill/9566

Improving AI Governance

AI Governance Board and Agency Policies

HHS is taking a multi-layered approach to promote sustained U.S. AI leadership in health care delivery, human services delivery, and public health. In addition to appointing an acting CAIO, HHS has established an AI Governance Board (AIGB). Led by Deputy Secretary Jim O'Neill, and comprised of Division leadership from across the Department, this group will meet at least twice per year and will oversee all major decisions related to AI across the Department. The AIGB will work closely with senior Department leaders in key areas: AI and IT policy, cybersecurity, data governance, procurement, privacy and civil rights, human resources, and administration. HHS has also convened a group of senior leaders in its Divisions to implement AI-related training, deployment, and innovation across the Department. The acting CAIO and AIGB will consult with these leaders on a regular basis about all matters pertaining to the governance, procurement, development and implementation of AI to align towards mission delivery. Together, these groups synthesize top-down direction from the Administration, other federal agencies, and HHS leadership with bottom-up innovation from HHS Divisions to implement HHS's vision for AI.

To facilitate implementation of HHS's vision for AI, the OCIO is currently reviewing and consolidating all existing IT policies and guidance. The Department is revising these policies for greater effectiveness and to scale and/or optimize existing processes that accelerate AI adoption and to dispense with burdensome and unmandated directives. Through this effort, HHS will incorporate necessary guidance specific to AI from the Administration (e.g., National Institute of Standards and Technology (NIST) AI-related cybersecurity controls[6]). Consistent with M-25-21, HHS is also actively developing a generative AI policy, an AI maturity model, and the FY25 HHS AI Use Case Inventory, all of which will enable robust governance of AI at HHS.

AI Use Case Inventory

In FY24, HHS reported 271 AI Use Cases across the Department. Commensurate with the Administrative priorities of AI adoption and use, preliminary analysis indicates that HHS may nearly double its reported AI use cases in FY25.

Throughout the remainder of FY25 and FY26, HHS will lay the groundwork to optimize the curation and maintenance of AI Use Case Inventory data and additional required analyses as

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[6] Control Overlays for Securing AI Systems | CSRC. https://csrc.nist.gov/News/2025/control-overlays-for-securing-ai-systems

well as the public release of code associated with applicable AI tools, where appropriate. To maximize utility, HHS anticipates developing:

- Standard operating procedures to accurately and comprehensively collect and report use cases;
- A standard taxonomy for categorizing use cases;
- Clear metrics to evaluate potential high-impact use as defined in M-25-21, as well as risk management practices for those use cases as they mature from pilot to development, in line with OMB guidance; and
- Avenues and best practices for sharing source data and code (where legally permissable).

Together, these resources will enable a OneHHS approach to diminish the annual burden of tracking AI innovation, limit redundant development of tools, encourage synergy and collaboration, and bolster, amplify, share, and scale successes.

Fostering Public Trust in Federal Use of AI

HHS is optimistic about the transformational potential of AI. Recent advances, from models that rapidly screen through and prioritize drug targets to AI-scribes that capture notes in clinical visits, suggest that AI may drive innovation in health care and human services faster and with greater impact than anticipated. However, our optimism is tempered with a deep sense of responsibility. By defining clear metrics of assessing HHS's AI use cases and sharing these evaluations publicly, HHS will continue to prioritize public transparency and accountability.

Determinations of Presumed High-Impact AI

HHS is working with Divisions to identify AI use cases that may be high-impact and to institute the necessary risk management practices stipulated therein. The HHS Acting CAIO will coordinate with appropriate officials overseeing these high-impact uses and determine to either certify waivers for implementation, to pause their operation until necessary risk management mitigations have been taken, or to halt them entirely.

Beginning in FY25, and throughout FY26, HHS will develop a standard operating procedure to cover the AI use case waiver process in accordance with the minimum requirements specified in M-25-21. HHS will use this process to review AI use case waivers and to make operational decisions regarding issuing, denying, revoking, and certifying waivers, as appropriate. By transparently sharing this streamlined process for colleagues across the Department, HHS will enable planning and mitigate administrative burden.

Implementation of Risk Management Practices and Termination of Non-Compliant AI

By April 3, 2026, except as prevented by applicable law and government-wide guidance, all HHS Divisions will work in concert with the HHS CAIO to apply the minimum risk management practices outlined in M-25-21 to high-impact AI. If Divisions are unable to meet this deadline, they will stop any applicable AI tool or solution until they achieve compliance. Prior to April 3, 2026, HHS will work with Divisions to bring potentially non-compliant AI use cases into conformity, which may include requests that third-party contractors and vendors voluntarily take appropriate action (e.g., via updated documentation or testing measures). The Department will ensure ongoing compliance with established minimum risk management practices such as the HHS ATO process.

Lastly, the Department will ensure ongoing compliance with established risk management practices as required by the Federal Information Security Modernization Act[7] of 2014 (FISMA) and articulated by the NIST Risk Management Framework[8] and the underlying cybersecurity and privacy controls outlined in NIST Special Publication (SP) 800-53 Revision 5, *Security and Privacy Controls for Information Systems and Organizations*.[9] These requirements are implemented through adherence to HHS's ATO process.

Conclusion

HHS is adapting its own internal operations to support the transformative potential of AI. As delineated in this Compliance Plan, HHS is removing barriers to the use of AI. Through AI innovation, improving AI governance, and fostering public trust in federal use of AI, HHS will update overly burdensome processes in favor of greater efficiency and effectiveness, and the Department will better fulfill its mission of improving the health and well-being of the American people.

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[7] S.2521 - 113th Congress (2013-2014): Federal Information Security Modernization Act of 2014 https://www.congress.gov/bill/113th-congress/senate-bill/2521
[8] NIST Risk Management Framework https://csrc.nist.gov/Projects/risk-management
[9] Security and Privacy Controls for Information Systems and Organizations https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r5.pdf