Bipartisan Policy Center

VIA ELECTRONIC SUBMISSION

February 23, 2026

Department of Health and Human Services
Office of the Secretary
7033A, 330 C Street SW
Washington, DC 20201

RE: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care

Dear Secretary Kennedy:

The Bipartisan Policy Center appreciates the opportunity to submit comments on the Department of Health and Human Services (HHS) Office of the Deputy Secretary and the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (RIN 0955-AA13).

The Bipartisan Policy Center and its advocacy affiliate, Bipartisan Policy Center Action (BPC Action), are unique in their approach to solving the nation's most pressing issues. As the only organization working across the full political spectrum on domestic issues, BPC brings together diverse perspectives to craft solutions that lower the everyday cost of living for families, expand opportunities, and strengthen the American economy.

BPC's Health Policy Program is dedicated to moving the U.S. toward a more cost effective, evidence-based health care system. We develop solutions focused on strengthening and sustaining Medicare and Medicaid, continuing the shift towards value, addressing inefficiencies and misaligned incentives within the health care system, and responsibly leveraging technology and innovation.

Our comments reflect BPC's extensive research and learnings from interviews with stakeholders and policy experts. Our comments here reflect BPC staff views and do not necessarily represent the official positions of BPC's founders or board of directors.

This letter includes BPC's comments on the areas highlighted by HHS in addition to select questions outlined in the request for information (RFI). While BPC did not comment on every provision in the proposed rule, such omissions should not be interpreted as a lack of interest in any particular provision.

Regulation

Artificial intelligence (AI) is increasingly embedded in the health care sector: automating administrative processes, transforming how we detect diseases, and guiding clinical decisions in real time. Yet there is no clear, integrated federal oversight system for tools that cross boundaries, particularly those that straddle consumer, clinical, and administrative functions.

As AI solutions become increasingly sophisticated and expand across clinical settings, they operate within a patchwork of federal rules, state laws, and voluntary industry standards. A fragmented and unclear federal policy landscape creates uncertainty for developers, complicates adoption for providers, and leaves gaps in patient protection. It also contributes to inefficiencies and unnecessary costs across the health care system.

While administrative AI tools[1] have gained traction—especially those supporting revenue cycle management—the clinical side lags outside of targeted applications such as medical imaging. Developers and health systems face high upfront costs, complex regulatory pathways, and limited reimbursement options. These market barriers suppress investment in clinical AI.

Targeted federal action can help shift these incentives. Recent investments in clinical AI research and development, including through the Advanced Research Projects Agency for Health (ARPA-H)[2] and the Administration for Community Living's (ACL's) Caregiver Artificial Intelligence Prize Competition,[3] signal growing federal interest in supporting responsible innovation with public benefit. Sustained and coordinated regulatory attention as well as the development of evidence-based standards to assess quality and value will be necessary to translate these investments into scalable clinical adoption.

In 2025, BPC mapped the complex federal regulatory and coverage landscape for health AI and highlighted key challenges and policy considerations. Below, we outline how oversight of an AI-enabled tool shifts depending on how and where a tool is used, not necessarily because of its technical design. We also note key considerations for policymaking. For more information, see:

- FDA Oversight: Understanding the Regulation of Health AI Tools[4]
- Oversight Beyond the FDA: Understanding the Regulation of Health AI Tools[5]

In the coming year, BPC plans to issue policy recommendations to accelerate adoption of high-value clinical AI solutions in health care. We look forward to sharing forthcoming publications, engaging in follow-up conversations, and supporting HHS and ASTP/ONC in advancing policies that enable innovation while ensuring responsible use of health AI and maintaining public trust.

U.S. Food and Drug Administration (FDA)

As the primary regulator of AI-enabled medical devices,[6] FDA regulations have major impacts on AI adoption and use in clinical care. FDA's oversight is grounded in premarket review and a risk-based approach to oversight, requiring that devices "demonstrate a reasonable assurance of safety and effectiveness." As of July 2025, the agency has authorized greater than 1,250 AI-enabled medical devices.

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[1] "Bipartisan Policy Center, *AI 101: Health Care Administration*, fact sheet, May 29, 2025, PDF, https://bipartisanpolicy.org/wp-content/uploads/2025/08/BPC_-Fact-Sheet-AI-101_Health.pdf.

[2] Advanced Research Projects Agency for Health, "ADVOCATE: Agentic AI-Enabled Cardiovascular Care Transformation," accessed February 20, 2026, https://arpa-h.gov/explore-funding/programs/advocate.

[3] Administration for Community Living, "The Caregiver Artificial Intelligence Prize Challenge," last modified February 5, 2026, https://acl.gov/caregiver-ai-competition.

[4] Maya Sandalow, Katie Adams, and Gabriel Loud, "FDA Oversight: Understanding the Regulation of Health AI Tools," Bipartisan Policy Center, November 10, 2025, Available at: https://bipartisanpolicy.org/issue-brief/fda-oversight-understanding-the-regulation-of-health-ai-tools/.

[5] Katie Adams and Maya Sandalow, "Oversight Beyond the FDA: Understanding the Regulation of Health AI Tools," Bipartisan Policy Center, June 20, 2025, Available at: https://bipartisanpolicy.org/report/oversight-beyond-the-fda-understanding-the-regulation-of-health-ai-tools/.

[6] Bipartisan Policy Center, *Health AI 101 Fact Sheet*, September 10, 2025, https://bipartisanpolicy.org/explainer/health-ai-101-fact-sheet-2/.

The vast majority use fixed, predictive algorithms, and the agency has not yet authorized devices that use generative AI.

New and accelerating AI capabilities raise complex regulatory questions. Below, we highlight key gaps and challenges:

- **Burden and uncertainty in pathways***:* Review pathways can be costly, complex, time-intensive and include regulatory grey areas (including disagreement about what types of AI software classify as a medical device or not). In certain cases, manufacturers have discontinued promising tools, citing the cost and complexity of obtaining FDA market authorization.[7] Others intentionally design tools to fall outside FDA jurisdiction; for example, by avoiding explicit medical claims or framing products as general wellness tools.

- **Regulatory fit for adaptive technologies***:* FDA frameworks were designed for static tools with specific indications. The FDA has introduced tools like Predetermined Change Control Plans, but there is still limited ability to update models or expand indications without new submissions. Most AI-enabled medical devices so far have been cleared via 510(k), which often does not require clinical trials and focuses on establishing similarity to an already authorized device. For Large Language Models (LLMs), evaluation is particularly challenging due to the large number of potential applications, output variability, and rapid changes.

- **Postmarket monitoring gaps***:* The FDA relies primarily on premarket review, and there is no standardized framework for evaluating AI tools once deployed. It has limited mechanisms to track real-world performance, model drift, and safety over time. For most AI-enabled devices, ongoing performance monitoring is not mandatory unless triggered by a specific requirement, such as a Section 522 order or a reportable adverse event. While some academic and health centers may have capacity for ongoing monitoring, many lower resourced and rural providers do not.

- **Limited workforce and resources***:* The FDA faces workforce and capacity constraints in evaluating complex AI technologies, especially those with unpredictable outputs. The agency is starting to use generative AI, with the goal of expediting FDA review, yet some agency staff and external stakeholders have expressed caution. For more information, see BPC's analysis, Mapping the Rise of AI in Federal Health Agencies.[8]

<u>Centers for Medicare & Medicaid Services (CMS)</u>
If the tool is used in care delivery to Medicare or Medicaid patients, including those in Medicare Advantage, CMS can influence its use through Conditions of Participation (CoPs)—the standards that providers must meet to receive payment.[9]

Key Considerations: Although CoPs do not yet include AI-specific requirements, they include requirements related to clinical oversight, documentation, and patient safety that may influence how

[7] Aaron E. Lottes et al., "Navigating the Regulatory Pathway for Medical Devices—A Conversation with the FDA, Clinicians, Researchers, and Industry Experts," *Journal of Cardiovascular Translational Research* 15, no. 5 (2022): 927–943, https://pmc.ncbi.nlm.nih.gov/articles/PMC8920055/.
[8] Amber Tran, Katie Adams, and Maya Sandalow, "Mapping the Rise of AI in Federal Health Agencies," Bipartisan Policy Center, August 10, 2025, Available at: https://bipartisanpolicy.org/article/mapping-the-rise-of-ai-in-federal-health-agencies/.
[9] Centers for Medicare & Medicaid Services, *Conditions for Coverage (CfCs) & Conditions of Participation (CoPs)*, last modified September 10, 2024, https://www.cms.gov/medicare/health-safety-standards/conditions-coverage-participation.

health systems integrate AI into care delivery. Below, we discuss CMS's influence through coverage and reimbursement policy.

ASTP/ONC

If a tool is integrated into a certified electronic health record (EHR) system, it may be subject to oversight from ASTP/ONC. Under its Health IT Certification Program, ASTP/ONC's HTI-1 rule[10] requires developers to disclose a tool's intended use, underlying logic, and data inputs, and to follow risk management practices—but only if the tool is part of a certified system. In December 2025, ASTP/ONC issued a deregulatory proposed rule[11] that would remove or revise the Health IT Certification Program criteria. If finalized, the HTI-5 proposed rule would significantly revise its decision support intervention certification criterion and remove AI transparency requirements.

Key Considerations: Current ASTP/ONC oversight applies only to those tools embedded in certified EHRs and supplied by the developer. It does not cover[12] third party tools (such as a clinical decision support app purchased separately and plugged into the EHR) or internally developed tools (such as an in-house model built by a hospital's IT team).

HHS Office for Civil Rights (OCR)

Once deployed, a tool that handles protected health information falls under the purview of the OCR, which enforces the Health Insurance Portability and Accountability Act (HIPAA). If a covered entity—such as a hospital or health plan—uses the tool, the vendor becomes a business associate and must comply with HIPAA's privacy and security rules. This relationship typically requires a Business Associate Agreement (BAA) outlining how personal information will be protected, used, and disclosed. Although an agreement imposes legal obligations on the vendor, it does not automatically make a product HIPAA-compliant. Compliance requires that the product itself implements appropriate safeguards, such as encryption, access controls, and audit capabilities.

OCR also enforces Section 1557 of the Affordable Care Act, which prohibits algorithmic discrimination[13] in federally funded health programs. Historically, OCR investigations could examine tools that result in disparate outcomes, even absent discriminatory intent. However, a 2025 Executive Order[14] instructs agencies to limit the use of disparate-impact analysis, signaling a likely shift in how OCR will prioritize and pursue such cases.

Key Considerations: HIPAA only applies to the traditional health care system—covered entities like hospitals, health plans, and their business associates. Tools that operate outside that system—such as

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[10] Department of Health and Human Services, *Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing*, 89 Fed. Reg. 1192 (January 9, 2024) (to be codified in 45 CFR pts. 170 & 171), https://www.federalregister.gov/documents/2024/01/09/2023-28857/health-data-technology-and-interoperability-certification-program-updates-algorithm-transparency-and.

[11] Department of Health and Human Services, *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity*, 90 Fed. Reg. 60970 (December 29, 2025) (to be codified in 45 CFR pts. 170 & 171), https://www.federalregister.gov/documents/2025/12/29/2025-23896/health-data-technology-and-interoperability-astponc-deregulatory-actions-to-unleash-prosperity.

[12] Maya Sandalow, "First Into the Breach: ONC Final Rule Addressing AI Transparency in Health Care," Bipartisan Policy Center, January 29, 2024, Available at: https://bipartisanpolicy.org/article/first-into-the-breach-onc-final-rule-addressing-ai-transparency-in-health-care/.

[13] Katie Adams, "Navigating AI in Health Care: HHS's Nondiscrimination Final Rule is in Effect," Bipartisan Policy Center, July 19, 2024, Available at: https://bipartisanpolicy.org/article/navigating-ai-in-health-care-hhss-nondiscrimination-final-rule-is-in-effect/.

[14] The White House, *Restoring Equality of Opportunity and Meritocracy*, April 23, 2025, https://www.whitehouse.gov/presidential-actions/2025/04/restoring-equality-of-opportunity-and-meritocracy/.

direct-to-consumer products, wellness apps, and services that don't bill insurance—are generally not subject to HIPAA, even if they collect sensitive health data. In those cases, the FTC may step in after the fact to enforce privacy and breach notification rules. This fragmented oversight leaves gaps in patient data protections and creates uncertainty for developers, providers, and other organizations deploying AI tools. It can also raise legal, liability, and operational costs and deter investment, particularly for smaller companies without in-house compliance teams.

FTC

If a tool is marketed directly to clinicians, patients, or consumers—especially through mobile apps or web platforms—it may fall under the FTC's jurisdiction. The FTC enforces the Health Breach Notification Rule, which requires companies to notify users if a breach involves personal data not covered by HIPAA. The agency also monitors marketing claims and can take action against companies that misrepresent a tool's capabilities or effectiveness. The FTC does not evaluate tools before they reach the market. Instead, it acts after harm or misrepresentation is reported.

Key Considerations: A tool's regulatory obligations may shift based on how it is marketed. The same product could fall under ASTP/ONC or FTC oversight depending on its platform and target audience. To assist developers, the FTC offers an interactive tool to help mobile health app developers identify which federal laws—such as HIPAA, the FTC Act, or the Health Breach Notification Rule—may apply to their product.

Reimbursement

As noted in the RFI, traditional fee-for-service (FFS) payments in Medicare often have misaligned incentives and are ill-suited for AI tools that don't fit traditional benefit categories or billing structures.[15] New technology, including AI, has historically driven efficiencies and lowered costs in sectors like manufacturing and agriculture. In health care, by contrast, new technologies often increase total spending due to expanded health care utilization and reimbursement incentives that reward adding services. BPC recently mapped the coverage and reimbursement landscape for health AI, and highlighted key challenges and policy considerations (summarized below). For more information, see:

- Paying for AI in U.S. Health Care[16]

In the coming year, BPC plans to recommend payment policy changes to incentivize adoption of high-value clinical AI solutions. As champions of health care affordability, BPC aims to ensure AI adoption improves patient outcomes and efficiency without increasing low-value costs. We look forward to sharing forthcoming publications, engaging in follow-up conversations, and supporting HHS in advancing policies that enable innovation while advancing responsible use of health AI and maintaining public trust.

- **AI use in clinical care is growing, but adoption remains limited and uneven**. As of 2025, there were only 24 AI-specific applications for CPT billing codes. Among billions of commercial claims

[15] Katie Adams and Julia Harris, "The AI Revolution in Health Care: Five Key Developments Policymakers Should Watch," Bipartisan Policy Center, November 21, 2024, Available at: https://bipartisanpolicy.org/explainer/ai-in-health-care-five-key-developments/.

[16] Gabriel Loud and Maya Sandalow, "Paying for AI in U.S. Health Care," Bipartisan Policy Center, February 18, 2026, Available at: https://bipartisanpolicy.org/issue-brief/paying-for-ai-in-u-s-health-care/.

between 2018 and June 2023,[17] only two AI tools had accumulated over 10,000 total claims, and only four had accumulated over 1,000. Medicare data reflect similar trends. Between 2018 and 2023, only three Medicare-covered AI tools[18] reached over 10,000 beneficiaries, and an additional five tools reached between 1,000 and 5,000 beneficiaries. Utilization of AI is much higher in wealthier, metropolitan ZIP codes as well as areas with academic medical centers. AI may offer the greatest clinical benefit for high-need patients,[19] including those with complex conditions and in underserved communities, but its use in these settings often requires stronger evidence and entails greater clinical risk. Fragmented payment for clinical AI tools may also contribute to uneven adoption in lower income communities, as well-resourced providers are better positioned to implement solutions despite limited reimbursement.

- **Most AI services don't align with existing payment structures**. Most AI doesn't fit into statutory Medicare benefit categories and is not reimbursed separately. Fragmented coverage and variable pricing slow effective AI adoption and reflect the limits of retrofitting AI into a volume-based system.

- **Value-based payment models may better support adoption of effective AI solutions without increasing low value spending**. AI tools increasingly assist clinicians through numerous mechanisms and across different types of care, enabling improved clinical capabilities and efficiency. These qualities challenge the fundamental nature of fee-for-service as a vehicle to pay for discrete services. Under Medicare's FFS payment system, stakeholders debate how to adequately price AI and whether to pay separately or include it within bundled payments. A system that pays for value of care rather than volume of services may more effectively incorporate AI advancements.

  In our September 2025 report, Toward Value and Sustainability: Medicare Part B Physician Payment and Related Reforms,[20] BPC issued policy recommendations to shift Medicare's current volume-based FFS system to a value-based one. One of our recommendations proposed reforming the Medicare Physician Fee Schedule to support clinicians' participation in APMs. Incentivizing participation in APMs is one lever that federal policymakers can utilize to accelerate adoption of AI-enabled tools. For example, newer payment models, such as CMS's Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) model, test Outcome-Aligned Payments (OAPs) for technology-supported care and may offer a more natural fit for high-value AI solutions.

- **Data gaps limit visibility into AI use and spending.** No public database tracks AI-specific billing, making it hard to assess adoption, costs, or value. Most AI tools use temporary billing codes

[17] Kevin Wu, Eric Wu, Brandon Theodorou, Weixin Liang, Christina Mack, Lucas Glass, Jimeng Sun, and James Zou, "Characterizing the Clinical Adoption of Medical AI Devices through U.S. Insurance Claims," *NEJM AI* 1, no. 1 (2024): AIoa2300030, https://doi.org/10.1056/AIoa2300030.

[18] Jared Augenstein, Nathan J. Pauly, and Ryan Vu, "AI-Enabled Care Is on the Rise for Medicare Beneficiaries—What Payors and Providers Need to Know," *Manatt Health*, November 17, 2025, https://www.manatt.com/insights/newsletters/health-highlights/ai-enabled-care-is-on-the-rise-for-medicare-beneficiaries-what-payors-and-providers-need-to-know.

[19] Peterson Health Technology Institute, *Clinical AI: Evidence and Policy Requirements for Scaling Adoption*, February 9, 2026, https://www.phti.org/wp-content/uploads/sites/3/2026/02/PHTI-Clinical-AI-Evidence-and-Policy-Requirements-for-Scaling-Adoption.pdf.

[20] Bipartisan Policy Center, *Toward Value and Sustainability: Medicare Part B Physician Payment and Related Reforms*, September 2025. Available at: https://bipartisanpolicy.org/report/toward-value-and-sustainability-medicare-part-b-physician-payment-and-related-reforms/.

without a set or guaranteed payment. Further, many codes don't distinguish between AI and non-AI services.

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?

A fragmented federal framework for AI regulation and reimbursement is a key barrier to private sector innovation in AI and its adoption in clinical care. Oversight responsibilities are distributed across multiple agencies and statutes, often based on context of use rather than risk or functionality. This fragmentation creates regulatory uncertainty for developers, complicates adoption for providers, and leaves gaps in patient protection. It also contributes to inefficiencies and unnecessary costs across the health care system.

Developers often report challenges navigating the FDA premarket approval process for AI-enabled tools. While FDA has taken steps to clarify expectations for software as a medical device, stakeholders note that existing pathways can be difficult to apply to rapidly evolving AI systems. Developers have cited the cost, uncertainty, and duration of premarket authorization as reasons for delaying, scaling back, or discontinuing clinically promising tools. Generative AI will present unique premarket evaluation challenges due to the large number of potential applications and output variability.

Even when AI-enabled medical devices successfully obtain FDA authorization, adoption barriers remain. Reimbursement pathways for clinical AI are limited and inconsistent, particularly for tools that support clinical decision-making rather than delivering discrete, billable services. As a result, health systems often struggle to justify the upfront investment and operational risk associated with deploying high-value clinical AI.

These dynamics shape product design choices. Some developers intentionally design tools to fall outside FDA jurisdiction; for example, by avoiding explicit medical claims or framing products as general wellness solutions. Many developers and health systems prioritize administrative AI applications—such as revenue cycle management tools designed to optimize billing—because they offer clearer and more immediate financial returns under existing payment systems. While these strategies can be economically rational, they may divert investment from more clinically integrated AI applications that could improve health outcomes and generate downstream cost savings.

Concerns about trust and liability also discourage health systems and clinicians from adopting advanced AI systems, such as autonomous AI. These barriers are outlined further in the PHTI report, which posits that "widespread adoption (of AI) will depend on building clinician confidence, gaining clarity about legal liability, and aligning payment models."[21]

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?

AI-enabled ambient scribes are among the most widely adopted AI tools in clinical care. These systems use natural language processing (NLP) and speech recognition to capture and transcribe patient–

[21] Peterson Health Technology Institute, *Clinical AI: Evidence and Policy Requirements for Scaling Adoption*, 2.

provider conversations into structured clinical notes. Early findings suggest ambient scribes appear to reduce cognitive load and burnout and improve the patient experience,[22] which may have downstream positive impacts on efficiency. The current evidence base for ambient scribes is still limited, including the extent to which they improve efficiency directly by reducing documentation time. More robust data is needed to assess whether they meet performance and cost expectations at scale.

AI-enabled tools have demonstrated potential to improve care and outcomes for people living with hypertension and mental health disorders, two common conditions that require ongoing management and where patients do not consistently receive adequate treatment.

- **Mental health chatbots**: Purpose-built mental health chatbots have increasingly entered the market and offer promising clinical outcomes for mental health patients. More than one in five U.S. adults live with a mental illness[23] but often these patients face barriers to care. Mental health chatbots offer a range of services spanning from more basic emotional support to clinical-grade psychotherapy that replicates or supplements human-based psychotherapy. Studies show that AI chatbots can provide crucial support[24] while patients wait for professional care and that they can significantly reduce symptoms of depression and anxiety.[25]

- **Autonomous prescribing for hypertension management**: For hypertension management, AI tools offer support across the care continuum, including remote blood pressure monitoring, risk detection, care navigation, medication initiation, and ongoing clinical management. These tools vary in their degree of human oversight from assistive AI to full autonomy. Studies demonstrate that assistive AI and semi-autonomous AI tools can provide safe, guideline-aligned medication management[26] to support blood pressure control.[27]

For more information on the opportunities for AI in hypertension and mental health care, as well as evidence requirements for scaling adoption, see PHTI report: Clinical AI: Evidence and Policy Requirements for Scaling Adoption.[28]

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.

Healthcare AI models need large, high-quality clinical datasets for robust training and analysis. Interoperability advances AI in health care by providing large volumes of standardized, high-quality data

[22] Peterson Health Technology Institute, *Adoption of AI in Healthcare Delivery Systems: Early Applications & Impacts*, March 2025, https://phti.org/wp-content/uploads/sites/3/2025/03/PHTI-Adoption-of-AI-in-Healthcare-Delivery-Systems-Early-Applications-Impacts.pdf.
[23] Substance Abuse and Mental Health Services Administration, *Highlights for the 2022 National Survey on Drug Use and Health*, 2022, https://www.samhsa.gov/data/sites/default/files/reports/rpt42731/2022-nsduh-main-highlights.pdf.
[24] M D Romael Haque and Sabirat Rubya, "An Overview of Chatbot-Based Mobile Mental Health Apps: Insights From App Description and User Reviews," *JMIR mHealth and uHealth* 11 (2023): e44838, https://mhealth.jmir.org/2023/1/e44838.
[25] Michael V. Heinz, Daniel M. Mackin, Brianna M. Trudeau, Sukanya Bhattacharya, Yinzhou Wang, Haley A. Banta, Abi D. Jewett, Abigail J. Salzhauer, Tess Z. Griffin, and Nicholas C. Jacobson, "Randomized Trial of a Generative AI Chatbot for Mental Health Treatment," *NEJM AI* 2, no. 4 (March 27, 2025): AIoa2400802, https://doi.org/10.1056/AIoa2400802.
[26] LeRoi S. Hicks, Thomas D. Sequist, John Z. Ayanian, Shimon Shaykevich, David G. Fairchild, E. John Orav, and David W. Bates, "Impact of Computerized Decision Support on Blood Pressure Management and Control: A Randomized Controlled Trial," *Journal of General Internal Medicine* 23, no. 4 (2008): 429–441, https://doi.org/10.1007/s11606-007-0403-1.
[27] Samal L, Kilgallon JL, Lipsitz S, et al. "Clinical Decision Support for Hypertension Management in Chronic Kidney Disease: A Randomized Clinical Trial," *JAMA Intern Med.* No. 184(5) (2024):484–492. https://doi:10.1001/jamainternmed.2023.8315.
[28] Peterson Health Technology Institute, *Clinical AI: Evidence and Policy Requirements for Scaling Adoption*.

that algorithms require. In our letter to CMS on the health technology ecosystem,[29] BPC discussed the need to align quality reporting requirements across payers and to leverage a common, interoperable data exchange framework.

A core element of U.S. interoperability is the Trusted Exchange Framework and Common Agreement (TEFCA), intended to build a unified, national approach to health information exchange. TEFCA shows potential in addressing longstanding barriers to seamless patient health information exchange across providers, payers, and patients. However, the Agreement needs stronger alignment with CMS-led payment reforms and broader health system transformations to fully realize its promise. As AI becomes more prominent in the health care technology landscape, its inclusion in interoperability standards will be necessary.

For AI-enabled tools, TEFCA could enable access to clinical data from across care settings and geographies. However, access to these data is currently limited. Developers generally need to partner with TEFCA participants, such as providers or health systems, and can only use data for certain purposes, typically treatment, payment, and health care operations. Broader use for activities like AI model development is generally not permitted under current rules without data de-identification or patient authorization; future updates to the framework could explore opportunities to safely expand permissible uses. Further unblocking and enhancing access to health data could fuel research and allow AI model development to support clinical care.

BPC is continuing to explore opportunities to strengthen interoperability across the health care system, including potential reforms to fully realize the potential of the TEFCA framework to advance the goals of value-based care. As outlined in our report on Medicare Part B payment reforms,[30] we recommended that Congress and the administration further incentivize participation in the health care data ecosystem to drive clinician participation in APMs. We expressed support for strengthening alignment between APMs and federal interoperability initiatives, including TEFCA and CMS's Interoperability Framework.

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

To accelerate the adoption of AI in clinical care, HHS could prioritize research that closes key data, evidence, and oversight gaps. Multiple agencies within HHS may have a role in addressing these areas.

Real-World Performance Monitoring

The FDA's current post-market mechanisms—such as the Medical Device Reporting (MDR) system and general Quality System Regulation (QSR) requirements—offer limited insight into how AI-enabled devices perform in real-world clinical settings. Challenges include tracking model drift, ongoing safety, and clinical validity over time. Experts have proposed frameworks for targeted, risk-based surveillance, including use of shared registries to monitor performance. The FDA could help to advance regulatory science related to AI oversight. This work might include exploring risk-based approaches to post-market monitoring and piloting efforts to use registries or structured real-world data. Broader coordination across HHS could help align monitoring and data-sharing practices.

Comparative Effectiveness and Clinical Outcomes Evidence

[29] Jonathan W. Burks, "Letter to CMS on Health Technology Ecosystem," Bipartisan Policy Center, June 13, 2025, Available at: https://bipartisanpolicy.org/testimony-letter/letter-to-cms-on-health-technology-ecosystem/.

[30] Bipartisan Policy Center, *Toward Value and Sustainability: Medicare Part B Physician Payment and Related Reforms*, 16.

Health care purchasers and clinicians often lack clear evidence on how AI-enabled tools perform, which can be a barrier to adoption. To be most useful, evidence on AI tools should compare performance to the current standard of care for the intended use. In some cases, the relevant comparison may be delayed, limited, or no care (e.g., a patient who turns to a mental health AI chatbot for support may otherwise have limited access to therapy). Research should prioritize clinically meaningful outcomes, rather than relying primarily on process measures. For additional discussion of best practices for evidence generation and performance monitoring, see Clinical AI: Evidence and Policy Requirements for Scaling Adoption.[31]

Several HHS agencies could help strengthen this evidence base. The Agency for Healthcare Research and Quality could support comparative effectiveness research in real-world settings, and the National Institutes of Health could support clinical research to validate AI tools across diverse populations and care environments. CMS could test promising approaches through demonstration authority, where appropriate. And the FDA and ASTP/ONC could clarify expectations for validation and ongoing performance reporting for AI integrated into regulated devices or certified health IT systems.

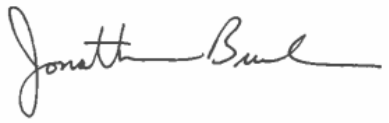
AI Billing and Reimbursement Data Infrastructure

Current billing and claims systems do not consistently distinguish AI-enabled services from traditional services. Many AI-related services have historically been captured using CPT Category III codes (emerging technology codes), which do not carry nationally established Medicare payment rates, and some codes can apply to both AI-enabled and non-AI services. This can make it difficult for analysts to separate AI use from other care in claims data and, as a result, limits policymakers' and researchers' view of adoption, utilization, and spending patterns. Efforts to enhance data infrastructure could improve this visibility.

Conclusion

BPC appreciates the opportunity to comment on this proposed rule. Please do not hesitate to contact me at JBurks@BipartisanPolicy.org if you would like to connect with BPC Health Policy Program staff for additional information.

Sincerely,



Jonathan Burks
Executive Vice President
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[31] Peterson Health Technology Institute, *Clinical AI: Evidence and Policy Requirements for Scaling Adoption*, 7.