AI in health care: a regulatory and legislative outlook

Updated September 2024

Building a better working world

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Advancements in artificial intelligence (AI), particularly the dawn of generative AI (GenAI) and products such as OpenAI's ChatGPT that can generate new content based on analysis of large amounts of data, have created global interest in how AI can change the way we work and live.

AI has experienced explosive growth, and the global market is projected to reach

$407b

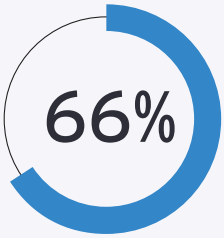
per year in revenue by 2027.[1]

The health care sector has been at the forefront of this evolution, using AI to forecast costs of care, recommend treatment options, discover new drugs, decipher images, streamline back-office functions and optimize supply chains. Future potential uses include helping predict the onset of disease and improving the precision of treatment options. Some have suggested that AI could be used to help temper rising federal and state health care costs.[2] In fact, a 2023 study estimated that AI could save $200 billion-$300 billion annually by creating more efficient health care processes, in addition to nonfinancial benefits such as improved quality, access, patient experience and clinician satisfaction.[3]

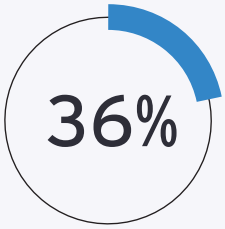
As the use of AI becomes more prevalent, and the tools' capabilities more advanced, many have raised concerns about its inherent risks. Stakeholders have also urged the government to take quick and decisive action to avert possible broader threats that weaponized and misaligned AI may pose to national and economic security.[4]

In the health care sector in particular, concerns have been raised about how some in the industry have been using AI — from leveraging AI to deny claims and relying on "black box" algorithms to driving clinical decision-making with limited human oversight and further entrenching implicit bias and discrimination in our health care delivery system, potentially undermining patient safety and privacy protections.[5]

According to the EY CEO Outlook Pulse survey



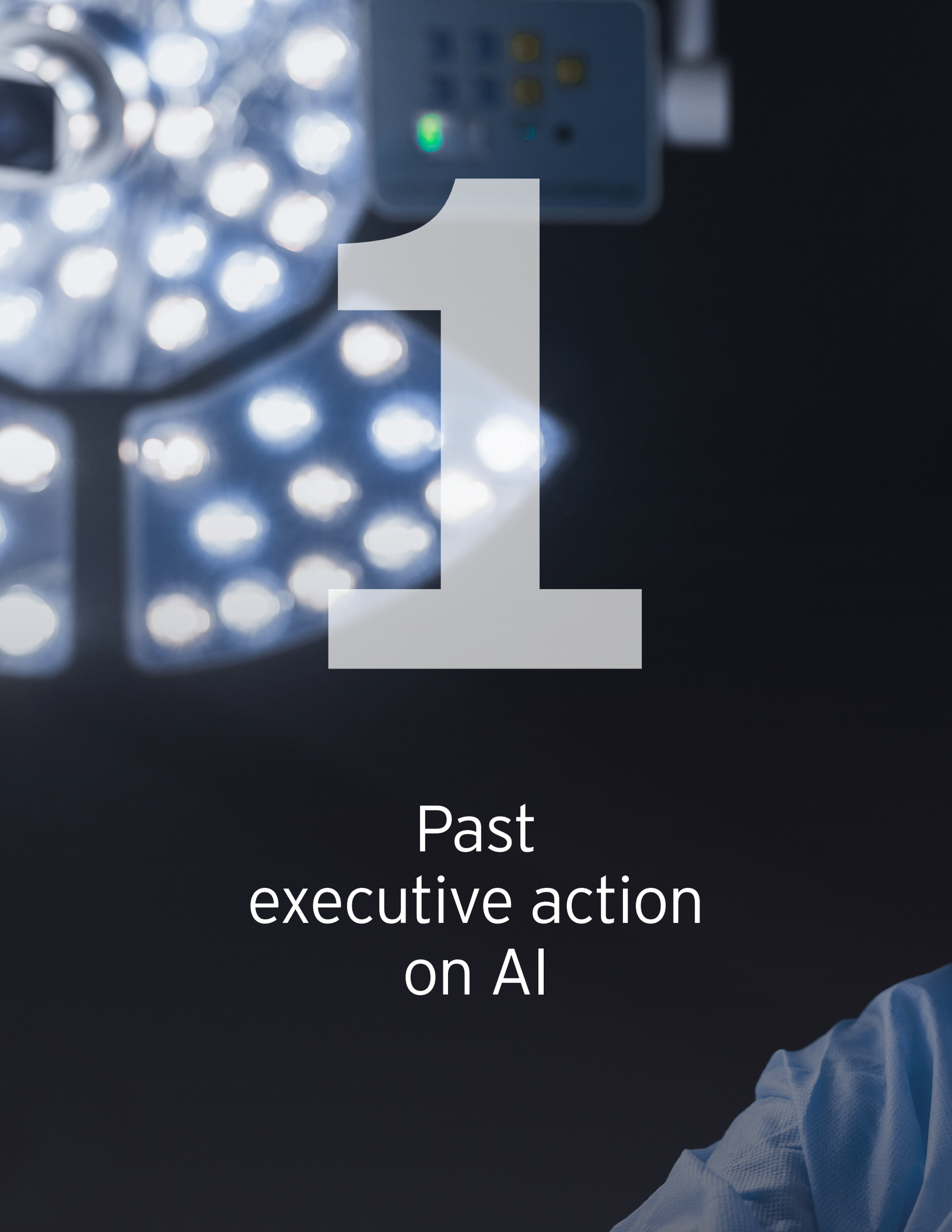
of global health care CEO respondents say more work is needed to address the social, ethical and criminal risks in an AI-fueled future. Yet only ...



said they had assessed how to effectively govern the risks unique to AI.

And although more than half of Americans surveyed believe GenAI will be common in health care within five years, they have mixed feelings about that use, with the majority falling somewhere between curious and concerned.[6] Another survey found that while many Americans acknowledged AI's potential to reduce bias and unfair treatment, 60% of Americans overall would be uncomfortable with a provider relying on AI when providing their health care.[7] Similarly, two-thirds of physicians are concerned about AI driving diagnosis and treatment decisions, despite 42% also being enthusiastic about AI's future in the workplace.[8]

As AI's presence continues to increase across the health care sector, the US has been slowly regulating the technology. Policymakers — many of whom are still working to understand AI and its potential — have expressed a desire to develop rules that balance care quality and safety with approaches that incentivize innovation. This brief explores some of the key legislative, regulatory and executive actions the US government has taken to date on the use of AI in the health care industry.



1

Past executive action on AI

The federal government has been laying the groundwork to advance responsible AI adoption for years. This includes the establishment of various AI oversight bodies across the federal government, executive actions and strategic initiatives.

Timeline of prior executive action

Trump administration Biden administration

June 2018: National Science and Technology Council's (NSTC) Select Committee on AI

- Established June 2018
- Advises the White House on interagency AI R&D priorities and improving the coordination of federal AI efforts to ensure continued US leadership in AI
- Goals include developing policies to prioritize and promote AI research and development, leveraging federal data and computing resources for the AI community, and training an AI-ready workforce.

December 2020: Executive Order on Promoting the Use of Trustworthy Artificial Intelligence in the Federal Government

- Issued by President Trump December 8, 2020
- Established principles for the use of AI in the federal government and a common implementation policy
- Directed agencies to catalog their AI use cases and called on the General Services Administration (GSA) and the Office of Personnel Management to enhance AI implementation expertise at the agencies

June 2021: Artificial Intelligence: An Accountability Framework for Federal Agencies and Other Entities

- Published by U.S. Government Accountability Office June 30, 2021
- Identifies key accountability practices – centered around the principles of governance, data, performance and monitoring – to help federal agencies and others use AI responsibly

February 2019: Executive Order on Maintaining American Leadership in Artificial Intelligence

- Issued by President Trump February 11, 2019
- Intended to spur the development and regulation of AI and fortify the US global position by directing agencies to prioritize investment in AI R&D
- Notes that leadership in AI is key to maintaining economic and national security and shaping the evolution of AI in a manner consistent with our nation's values, polices and priorities

January 2021: National AI Initiative Office

- Mandated by the National Artificial Intelligence Initiative Act of 2020
- Established to provide technical and administrative support to the Interagency Committee on AI and the National AI Advisory Committee
- Oversees interagency coordination and promotes access to technologies, innovations, best practices and expertise derived from initiative activities at other federal agencies

April 2022: National AI Advisory Committee

- Mandated by the National AI Initiative Act
- Consists of experts with a broad and interdisciplinary range of AI-relevant experience from across the private sector, academia, nonprofits, and civil society
- Tasked with advising the President and the National AI Initiative Office on AI-related topics

May 2022: National Artificial Intelligence Research Resource (NAIRR) Task Force and Roadmap

- Submitted an interim report to the President and Congress setting forth the Task Force's vision for the NAIRR
- Subsequently published Strengthening and Democratizing the U.S. Artificial Intelligence Innovation Ecosystem, an implementation plan and roadmap for standing up a national research infrastructure that would broaden access to the resources essential to AI research and development

June 2022: GSA's AI Center of Excellence

- Published the AI Guide for Government, intended to help government decision-makers understand AI implications for their agencies, how to invest and build AI capabilities, and what to consider as they invest in AI and prepare for its enterprise-wide use

October 2022: Blueprint for an AI Bill of Rights

- Released by White House Office of Science and Technology Policy
- Reflects Biden Administration focus on addressing potential of AI to deepen discrimination and address people's rights and safety, identifying five principles to guide the design, use, and deployment of automated systems to protect the public in the age of AI
- Includes a focus on enhanced protections and restrictions for data and inferences related to sensitive domains, including health
- Details the potential for algorithmic discrimination in health care specifically and provides examples of human "alternatives" to AI and other implementation considerations to ensure rights are protected

January 2023: National Institute of Standards and Technology (NIST) AI Risk Management Framework

- As directed by the National Artificial Intelligence Initiative Act of 2020, began development of an AI Risk Management Framework (AI RMF) in collaboration with the private and public sectors "to better manage risks to individuals, organizations, and society associated with AI"
- Intended for voluntary use, it serves as a "living document" to ensure trustworthy design, development, use and evaluation of AI
- AI RMF 1.0 released by NIST January 26, 2023, following years of collaboration with private and public sectors

February 2023: Focus on combating algorithmic discrimination in Racial Equity EO

- Executive Order to Further Advance Racial Equity and Support for Underserved Communities Through the Federal Government signed by President Biden February 16, 2023
- Included instructions to agencies to focus their civil rights authorities on emerging threats, including algorithmic discrimination in automated technology

March 2023: Trustworthy and Responsible AI Resource Center

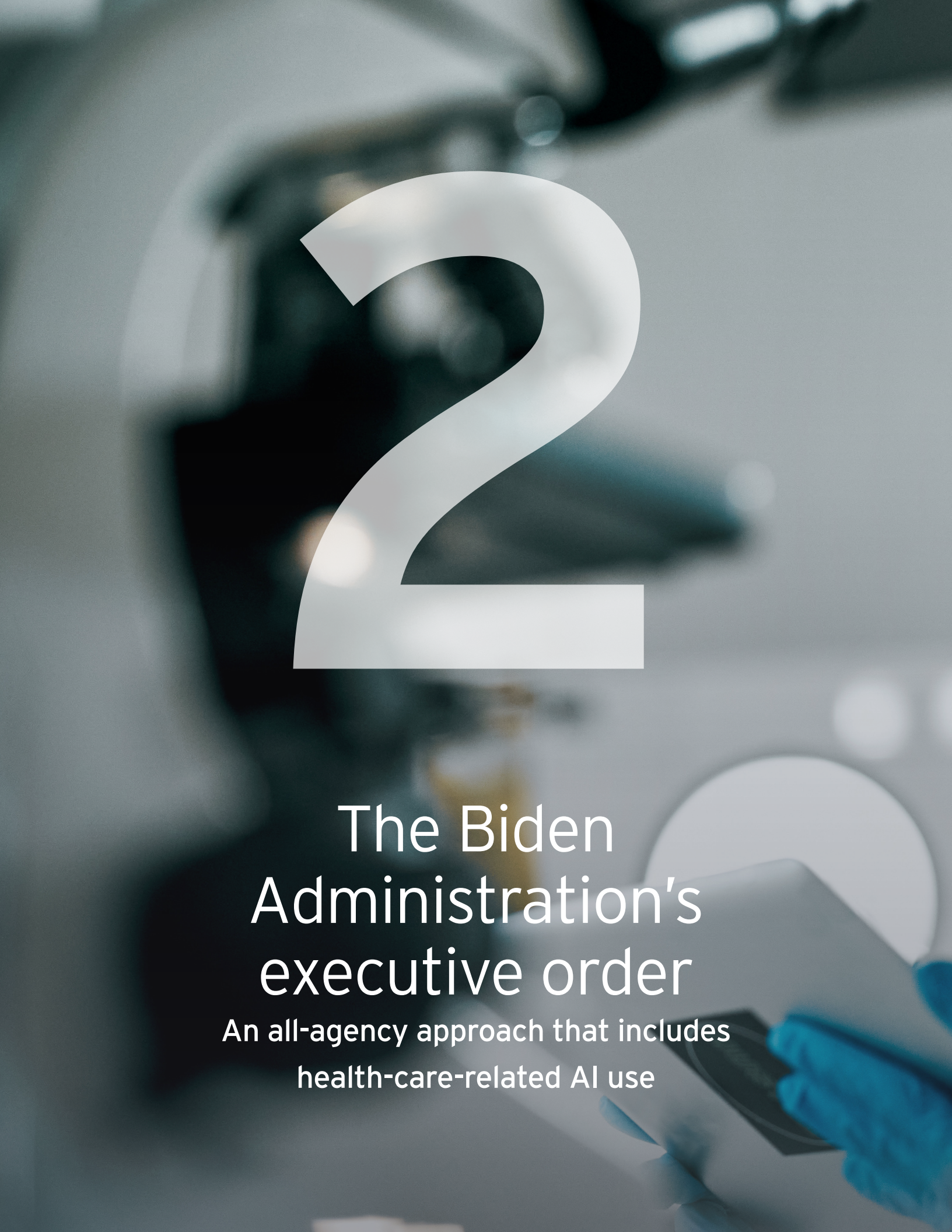
- Launched by NIST March 30, 2023, to facilitate implementation of, and international alignment with, the AI RMF
- Articulates characteristics of trustworthy AI: valid and reliable, safe, secure and resilient, accountable and transparent, explainable and interpretable, privacy-enhanced, and fair with harmful bias managed
- Plans to evaluate AI RMF effectiveness in future
- Has also published other guidance documents, including a special publication, Towards a Standard for Identifying and Managing Bias in AI

May 2023: Strategic Plan on National AI Research and Development

- Update to the National AI Research and Development Strategic Plan released by White House, reaffirming the federal government's commitment to smart investments in R&D that promote responsible innovation and advance solutions to societal challenges – including public health and health care – while mitigating potential risk
- Serves as a roadmap for driving progress, outlining the major research challenges to coordinate and focus federal R&D investments and to ensure continued US leadership in the development and use of trustworthy AI systems

October 2023: EO on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence

- Executive Order to develop a coordinated, all-of-government approach to governing the development and use of safe and responsible AI
- Tasks federal agencies with tackling the use of AI in their specific areas, including consideration of potential regulatory action and internal capacity development
- Followed by OMB memo establishing agency requirements and guidance for AI governance, innovation, and risk management



2

The Biden Administration's executive order

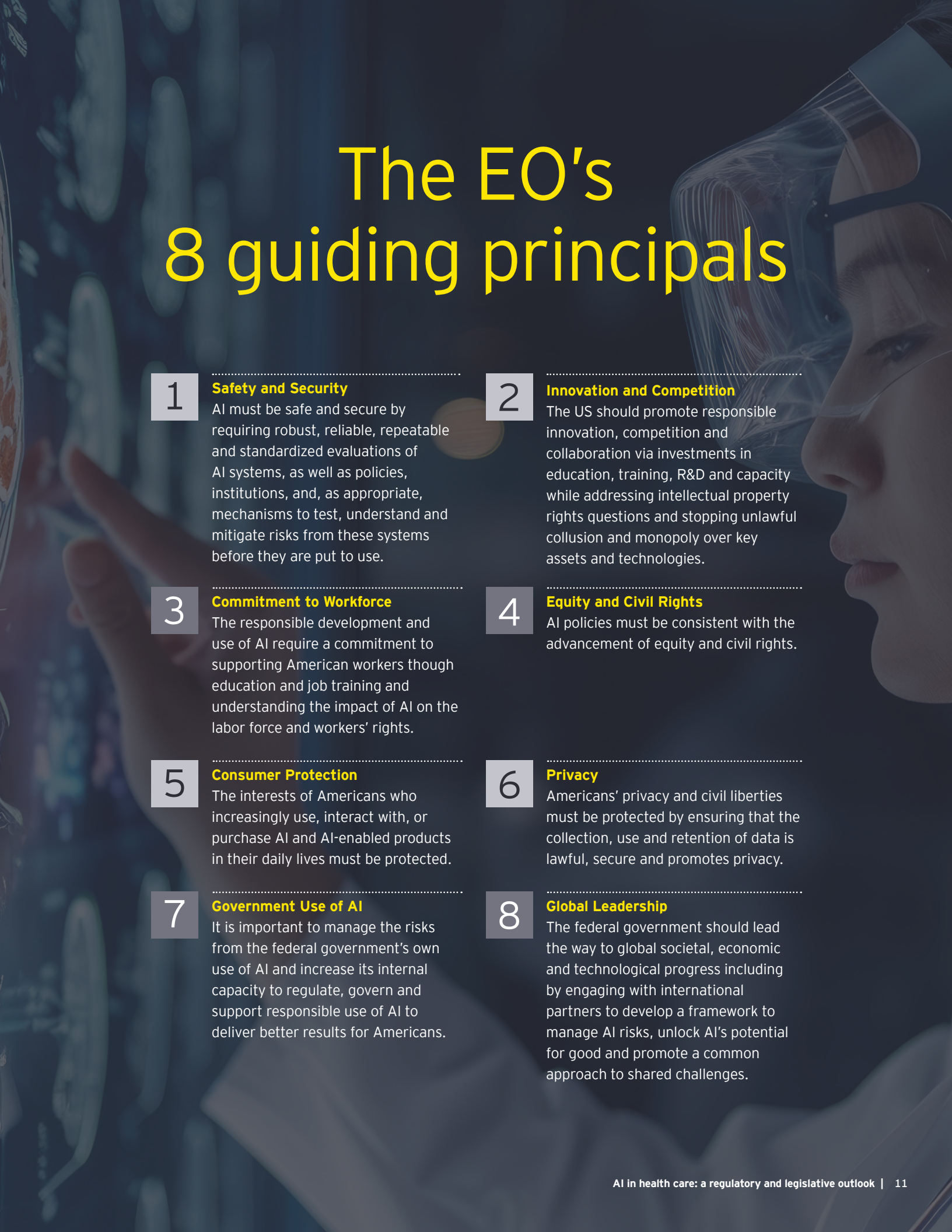
An all-agency approach that includes health-care-related AI use

On October 30, 2023, President Biden unveiled a sweeping executive order (EO) that aims to develop a coordinated, all-of-government approach to overseeing the development and use of safe and responsible AI.

It builds on prior White House activity, including an AI Bill of Rights, EO on algorithmic discrimination and strategic plan on national AI research and development. Organized across eight guiding principles (see next page), the EO tasks federal agencies with tackling the use of AI in their specific areas. It requires them to issue guidance documents and consider potential future regulatory action, and to provide instructions regarding the use and procurement of AI, as well as accelerating AI-related hiring and internal capacity development.

Among other items, the EO tasks NIST with building on its previous work to develop guidelines and leading practices to promote consensus industry standards that will encourage the development and deployment of safe, secure and trustworthy AI systems. It also leverages the Defense Production Act to require foundation models – powerful models trained on broad data and applicable in a wide range of contexts that might present risks to national security or public health – to share safety test results and other critical information with the federal government.

On November 1, 2023, shortly following the EO release, the Office of Management and Budget (OMB) issued a draft memorandum – finalized March 28, 2024 – instructing agencies on next steps to advance AI governance and innovation while managing AI risks, particularly for those deemed to be "safety-" or "rights-impacting." According to the memorandum, agencies must follow certain minimum practices for AI that impacts rights and safety if the AI is used to control or meaningfully influence the outcomes of certain activities or decisions. In health care, this includes a long list of items: decisions regarding medical devices, medical diagnostic tools, clinical diagnosis and determination of treatment, medical or insurance health-risk assessments, drug-addiction risk assessments and associated access systems, suicide or other violence risk assessment, mental-health status detection or prevention, systems that flag patients for interventions, public insurance care-allocation systems, or health-insurance cost and underwriting processes.



The EO's 8 guiding principals

1 **Safety and Security**
AI must be safe and secure by requiring robust, reliable, repeatable and standardized evaluations of AI systems, as well as policies, institutions, and, as appropriate, mechanisms to test, understand and mitigate risks from these systems before they are put to use.

2 **Innovation and Competition**
The US should promote responsible innovation, competition and collaboration via investments in education, training, R&D and capacity while addressing intellectual property rights questions and stopping unlawful collusion and monopoly over key assets and technologies.

3 **Commitment to Workforce**
The responsible development and use of AI require a commitment to supporting American workers though education and job training and understanding the impact of AI on the labor force and workers' rights.

4 **Equity and Civil Rights**
AI policies must be consistent with the advancement of equity and civil rights.

5 **Consumer Protection**
The interests of Americans who increasingly use, interact with, or purchase AI and AI-enabled products in their daily lives must be protected.

6 **Privacy**
Americans' privacy and civil liberties must be protected by ensuring that the collection, use and retention of data is lawful, secure and promotes privacy.

7 **Government Use of AI**
It is important to manage the risks from the federal government's own use of AI and increase its internal capacity to regulate, govern and support responsible use of AI to deliver better results for Americans.

8 **Global Leadership**
The federal government should lead the way to global societal, economic and technological progress including by engaging with international partners to develop a framework to manage AI risks, unlock AI's potential for good and promote a common approach to shared challenges.

Actions instructed by the EO and final OMB guidance that implicate the U.S. Department of Health and Human Services (HHS) specifically include:

Deadline	Action	Status
January 2024 (EO)	HHS, in consultation with the Department of Defense (DOD) and Department of Veterans Affairs (VA), must establish an HHS AI Task Force that will develop a strategic plan for policies and regulatory action on the responsible deployment of AI/machine learning (ML) technologies used in the health sector (e.g., R&D, drug and devices, health care delivery and financing, public health)	Complete
April 2024 (EO)	HHS shall consider appropriate actions to advance the understanding of, and compliance with, federal nondiscrimination laws by health and human services providers that receive federal financial assistance, and how such laws relate to AI.	Complete
April 2024 (EO)	HHS must develop a strategy to determine whether AI/ML technologies maintain appropriate levels of quality.	Complete
May 2024 (OMB guidance)	HHS must designate a Chief AI Officer (CAIO) and abide by specific roles, responsibilities and reporting structures for agency CAIOs and governance bodies.	Complete
May 2024 (OMB guidance)	Convene agency AI Governance Board.	Complete
October 2024 (EO)	HHS, in consultation with DOD and VA, must establish an AI safety program in partnership with voluntary federally listed Patient Safety Organizations to (1) Establish a framework to identify clinical errors in AI health technologies and specifications for a tracking repository for incidents that cause harm or bias, and (2) Analyze data to develop recommendations, best practices or guidelines to prevent clinical errors.	Pending
October 2024 (EO)	HHS should develop a strategy for regulating the use of AI or AI-enabled tools in drug-development processes.	U.S. Food and Drug Administration (FDA) issued two discussion papers to inform future strategy.
December 2024 (OMB guidance)	HHS must implement minimum practices for safety-impacting or rights-impacting AI and provide transparency to the public. This includes uses involved in health, employment, federal benefits, critical infrastructure and more. Also stop using AI not in compliance that does not have a waiver or extension. Must also conduct periodic risk reviews and certify ongoing validity of waivers granted (and additional reporting requirements).	Pending and annually
March 2025	Develop a strategy for identifying and removing barriers to responsible use of AI and enterprise-wide advances in AI maturity.	Pending
Annually	Publicly release an expanded AI use case inventory and report metrics on use cases not included in public inventories.	Ongoing
Annually	Share and release AI code, models, and data assets, as appropriate.	Ongoing

On January 29, 2024, the White House celebrated nearly 30 actions completed under the EO's first 90-day deadlines and on April 29, 2024, announced actions met by the EO's 180-day deadlines.

Recent activities instructed by the EO include:

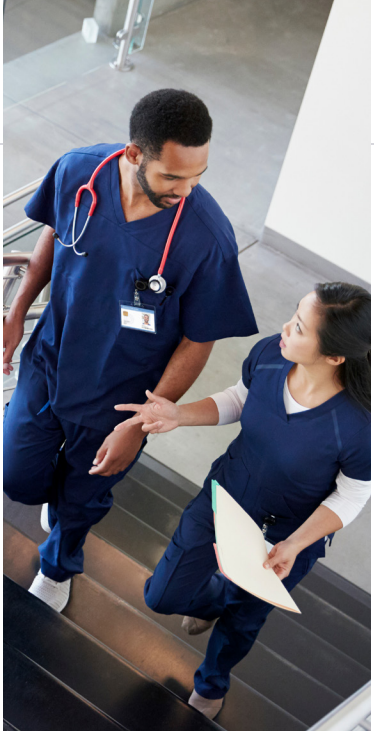
Compelling developers of "the most powerful AI systems" to report vital information, including AI safety test results, to the Department of Commerce	Launching a pilot of the NAIRR to catalyze broad-based innovation, competition and equitable access to AI	Initiating an AI Talent Surge to accelerate hiring of AI professionals across the federal government
Publishing guidance and principles that set guardrails for the responsible and equitable use of AI in administering public benefits programs, including for programs like SNAP and benefits programs overseen by HHS	Finalizing a rule clarifying that nondiscrimination requirements in health programs and activities continue to apply to the use of AI, clinical algorithms, predictive analytics and other tools	Developing a strategy for ensuring the safety and effectiveness of AI deployed in the health care sector

HHS also established an AI Task Force to "develop policies to provide regulatory clarity and catalyze AI innovation in health care." One of its assignments is to develop ways to evaluate how AI-enabled tools and frameworks can use AI "to advance drug development, bolster public health, and improve health care delivery," among other imperatives. To date, the Task Force has published guiding principles for addressing racial biases in health care algorithms.

The Biden Administration has pulled other levers with a stated goal of advancing responsible AI. In July 2023, the Administration secured commitments from 15 leading AI companies to develop responsible AI with the goal of moving "toward safe, secure and transparent development of AI technology," as well as voluntary commitments from 28 health care providers and payers to commit to the "safe, secure and trustworthy purchasing and use of AI" in health care. The commitments serve to align industry action on AI around the "FAVES" principles – that AI should lead to health care outcomes[9] that are Fair, Appropriate, Valid, Effective and Safe.

3

Health agency activity



HHS: AI governance and strategy

While the EO tasks HHS with new imperatives, addressing AI is not new to the agency.

HHS has had an established AI office since March 2021, the Office of the Chief AI Officer (OCAIO). The OCAIO was established under EOs issued under former President Trump with stated goals of "maintain[ing] American leadership in AI" and "promot[ing] the use of trustworthy AI." The OCAIO aims to facilitate effective collaboration on AI efforts across HHS agencies and offices and "drive implementation of the HHS AI strategy." It developed the HHS Trustworthy AI (TAI) Playbook in 2021 and is tasked with carrying out the recent Biden EO and facilitating the development of agency activities to meet the directives.

In July 2024, HHS announced a department-wide restructuring aimed to "streamline and bolster technology, cybersecurity, data, and [AI] strategy and policy functions."[10] The Office of the National Coordinator for Health Information Technology (ONC) was renamed the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC), with oversight over technology, data and AI policy and strategy, including the HHS-wide roles of Chief Technology Officer, Chief Data Officer, and Chief AI Officer. National Coordinator Micky Tripathi was named Assistant Secretary for Technology Policy/National Coordinator for Health Information Technology in addition to his role as the department's Acting Chief AI Officer.

> "We in the department are AI optimists ... AI-based technologies have the potential to accelerate innovation, increase competition, help to ameliorate health inequities, reduce clinician burnout, and improve care and the care experience for patients.
>
> Micky Tripathi, Assistant Secretary for Technology Policy, National Coordinator for Health Information Technology, and Acting Chief AI Officer.

Tripathi testified that HHS is prioritizing five AI-related activities[11]

1. **Develop resources and policies**
   to enable the safe, responsible adoption and use and manage risks of AI in health care, public health and human services.
2. **Advance quality and safety of AI in health**
   through assurance standards and quality management processes.
3. **Leverage grantmaking and contracting**
   to advance the development and responsible use of AI across the health and human services delivery value chain.
4. **Provide public education**
   across the health care ecosystem and constituents – from individuals to organizations and states – on AI development and use in health and human services delivery.
5. **Evaluate and deploy AI capabilities**
   across HHS to drive process innovation and modernization.

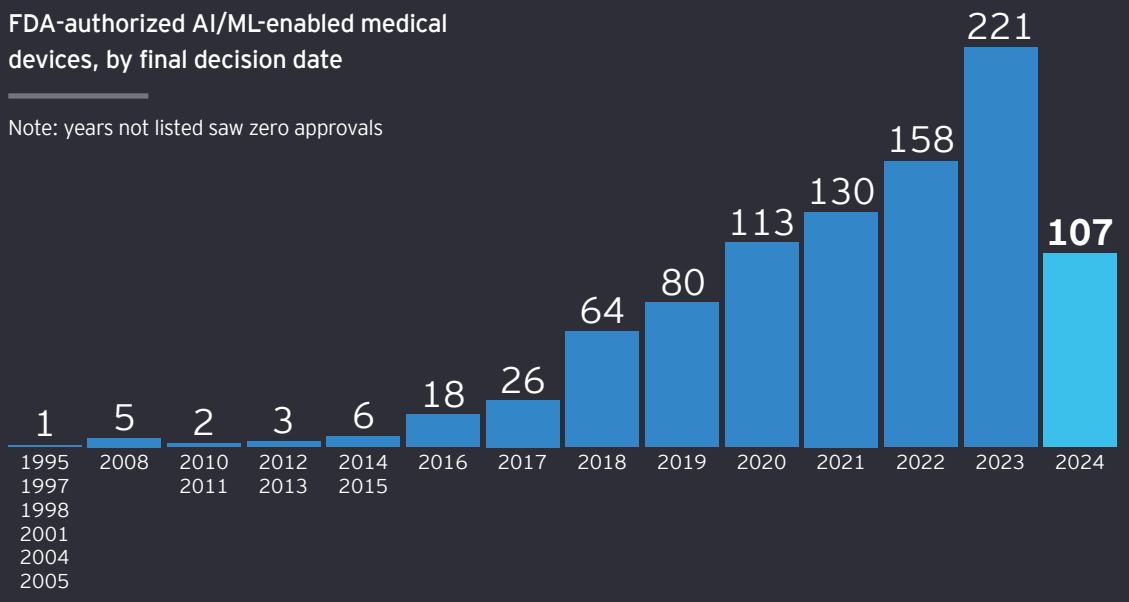
Spurred by President Biden's recent EO and a growing industry and intra-agency imperative, HHS is expected to continue to consider AI in future rulemaking, guidance and enforcement. HHS is tasked by the EO with a particular focus on potential implications for health and safety risks, safeguarding civil rights and consumer protections and protecting against infringements on privacy, unintended bias or discrimination, and other potential harms. Over the past several years, the agency has ramped up its actions on AI, increasingly approving AI/ML-enabled devices, creating a new digital advisory committee and regulating the use of AI in medical necessity and algorithmic transparency.

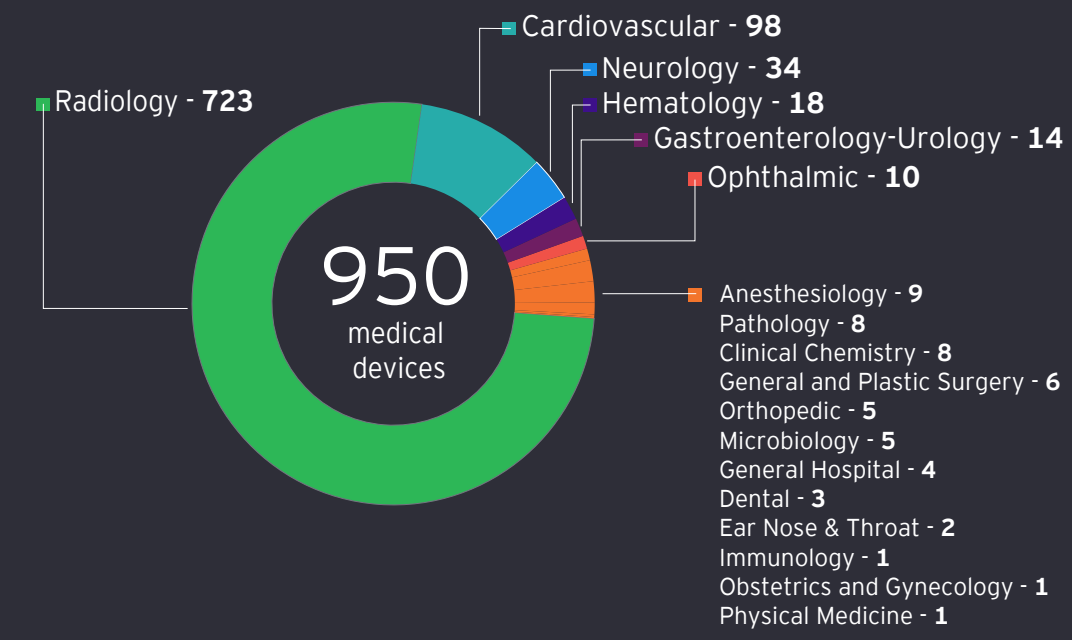
Some agencies have also suggested that Congress must act for those agencies to more adequately regulate AI in the future. For example, the FDA told the GAO – Congress' oversight arm – that the FDA needs more premarket review and post-market surveillance authority, as well as more flexibility to tailor its premarket review process to AI/ML, to avoid evaluating the emerging technology through outdated lenses. The FDA also indicated in a recent paper that some AI products, such as chatbots or those that summarize doctors' notes, would not be considered medical devices subject to FDA rules, thus the agency would need more explicit new authority from Congress to oversee those products. FDA Commissioner Robert Califf told stakeholders, "we'd need another doubling of size" to evaluate AI because unlike precursor technologies, AI/ML-enabled products will require shifting from one-time approval processes to ongoing oversight.[12]

Health agencies have taken action to address AI

- **Report outlining FDA focus areas for AI and medical products:** In March 2024, the FDA released a report laying out its focus areas for the development and use of AI across the medical product lifecycle. In addition to finalizing guidance on marketing submission recommendations for predetermined change control plans for AI-enabled device software functions, the FDA also plans to issue draft guidance on lifecycle management considerations and premarket submission recommendations, along with draft guidance on considerations for the use of AI to support regulatory decision-making for drugs and biological products. The report also outlines other planned efforts, including clarifying industry best practices and launching efforts to fill in gaps in AI knowledge and regulatory science, along with a range of demonstration projects to detect and mitigate bias in AI development.
- **Use of RWE to support regulatory decision-making for medical devices:** On December 19, 2023, the FDA released draft guidance for generating real world evidence (RWE) from real world data (RWD) that the agency will use, if finalized, for medical device reviews and regulatory decisions. The draft guidance mentions AI and software-only medical devices, implying that RWD could be used to "train" AI/ML-enabled medical devices, and stresses the need to minimize bias in data and privacy practices to protect patient data.
- **Approval of AI-enabled devices:** As of May 13, 2024, the FDA had approved 882 AI/ML-enabled medical devices, including 221 in 2023 and 45 in the first few months of 2024 (see figure 1).

Figure 1: FDA rapidly increasing approvals for AI/ML-enabled medical devices





- **Creation of Digital Health Advisory Committee:** On October 11, 2023, the FDA announced the creation of a new Digital Health Advisory Committee to explore scientific and technical issues related to digital health technologies (DHTs) including AI. The Committee will work to improve the FDA's understanding of the benefits, risks and clinical outcomes associated with DHTs, including analysis of potential or established FDA policy or regulation and use in clinical trials or post-market studies.

- **Discussion paper on use of AI/ML in drug development:** On May 11, 2023, the FDA issued a discussion paper on the use of AI/ML in the development of drugs and biologics, aimed at informing future rulemaking and promoting mutual learning and discussion with stakeholders. The agency solicited feedback on the opportunities and challenges involved in using AI/ML in the development of drugs, as well as medical devices intended to be used with drugs.

- **Draft guidance proposing Predetermined Change Control Plans:** On April 3, 2023, the FDA issued draft guidance for a Predetermined Change Control Plan (PCCP) for AI/ML-Enabled Device Software Functions, which outlined a process for companies to disclose planned updates to their algorithms to ensure that AI/ML-enabled medical devices can be safely, effectively and rapidly modified, updated and improved in response to new data. This draft was followed by joint guiding principles with Canada and the UK intended to encourage international harmonization and lay a foundation for PCCPs for ML-enabled medical devices.

- **Proposed regulatory framework, action plan and best practices for modifications to AI/ML-based software as a medical device (SaMD):** On April 2, 2019, the FDA published a discussion paper that described a potential approach to premarket review for AI and ML-driven software modifications. Following this, in January 2021, the FDA published an AI/ML SaMD Action Plan. Consistent with the action plan, the FDA later issued several other guidance documents, including guiding principles for ML in medical device development.

- **The Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC) ONC HTI-1 rule:** On December 13, 2023, ONC issued the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Final Rule, which creates new technical transparency and risk-management requirements for AI-enabled health IT products that interface with electronic health records (EHRs) to aid in clinical decision-making. The rule aims to fill a gap in regulation to help providers choose safer AI that abides by the FAVES principles. Developers that want to certify their AI-enabled health IT products through ONC will be required to describe how their algorithm was designed, developed and trained, and whether patient demographic, social determinants of health or other equity-related data were used in training the AI model. Developers must also provide information for clinical users about how to assess them using FAVES. The regulations will apply at the end of 2024, and while the certification process is voluntary, 97% of hospitals and almost 80% of physician offices across the country use ONC-certified EHRs.

The Centers for Medicare & Medicaid Services (CMS)

- **Requirements for Medicare Advantage individual medical necessity determinations that use algorithms or software tools:** CMS is exploring whether algorithms used by health plans and providers to identify high-risk patients and manage costs can introduce inappropriate bias and restrictions into medically appropriate care delivery. As of January 2024, CMS is requiring Medicare Advantage (MA) organizations to ensure that they are making medical necessity determinations based on the circumstances of the specific individual, as opposed to using an algorithm or software. In February 2024, CMS issued FAQs to clarify that algorithms or software tools can assist plans in making coverage determinations but that the MA organization is responsible for ensuring it complies with all coverage determination rules.

- **CMS AI Playbook:** In October 2022, CMS created an AI Playbook to serve as a "how-to" manual with detailed guidance on key design principles, best practices, and step-by-step instructions for building mission-critical, trustworthy AI solutions. It also outlines a governance framework defining the principles and practices an organization should follow to address the societal, ethical and legal impacts of AI.

- **AI Health Outcomes Challenge:** The CMS Innovation Center (CMMI) conducted an AI Health Outcomes Challenge from 2018 to 2021 to accelerate the development of AI tools — such as deep learning and neural networks — for predicting patient health outcomes for Medicare beneficiaries.

- **CMS programs and initiatives:** CMS also has various programs and initiatives intended to apply AI techniques within CMS to increase efficiency, improve health outcomes and detect waste, fraud and abuse. This includes the AI Explorers Program, where CMS employees prototype AI applications for testing and potential development, and an AI/ML track of CMS's Workforce Resilience Program, where participants learn about AI/ML and eventually how to operationalize AI methods and explore use cases at CMS.

The National Institutes of Health (NIH)

- **Investments in AI to advance research:** The NIH is utilizing AI to research priority areas, including cancer, Alzheimer's disease, and mental illness, investing at least $200m in FY2023 and approximately $175m in FY2022 in the use of large data sets. NIH also issued a Notice of Funding Opportunities (NOFO) to develop AI/ML tools and resources to support the NIH Brain Initiative and a Notice of Special Interest (NOSI) to help improve the usability of NIH-supported data for AI/ML analytics.
- **AIM-AHEAD program:** In 2021, NIH launched the AI/ML Consortium to Advance Health Equity and Researcher Diversity (AIM-AHEAD) program, which will establish partnerships to increase the participation and representation of researchers and communities currently underrepresented in the development of AI/ML models and to enhance the capabilities of this emerging technology.
- **Data-driven initiatives:** The NIH is working to create and implement large and far-reaching applications using AI and its components. The effort makes a wealth of biomedical data available to research communities and aims to make these data "findable, accessible, interoperable, and reusable" — or FAIR. Additionally, the NIH seeks to make these data usable with AI/ML applications. The NIH is engaging in several initiatives aimed at catalyzing new opportunities in AI and data science, propelling biomedical research and AI/ML technologies forward, and setting the stage for widespread and representative adoption.

The Advanced Research Projects Agency for Health (ARPA-H)

- **Improving chatbots for health care:** On May 2, 2024, ARPA-H announced a new endeavor, CARE (Chatbot Accuracy and Reliability Evaluation) ET (Exploration Topic), which will fund the development of novel technical approaches to improve the testing and evaluation of chatbot outputs for patient-facing applications, with a focus on public-facing chatbots.
- **MATRIX project:** ARPA-H announced in February 2024 a new project, the ML/AI-Aided Therapeutic Repurposing In eXtended uses (MATRIX) project, which intends to build an ML platform to rapidly pinpoint and validate existing medications to treat diseases that currently have no therapies.

Other HHS activities

- The Office for Civil Rights (OCR) finalized a rule on April 26, 2024, to clarify that federal civil rights laws to prevent discrimination in health programs and activities under Section 1557 of the Affordable Care Act (ACA) include the use of telehealth and patient care decision support tools including AI/ML.
- The Agency for Healthcare Research and Quality (AHRQ) released an evidence review in 2022 summarizing research on racial and ethnic bias in health care algorithms and approaches to mitigate bias and reduce disparities. In March 2023, AHRQ published a conceptual framework to apply guiding principles across an algorithm's lifecycle to address structural racism and discrimination, centering on health care equity, and in December 2023 it published a paper in ***JAMA*** on the topic.
- The Centers for Disease Control and Prevention (CDC) is exploring how AI and natural language processing methods can enhance public health's ability to estimate US suicide fatalities and other events. The CDC also uses AI to aid in the response to disease outbreaks and the opioid epidemic.
- The Administration for Strategic Preparedness and Response (ASPR) currently leverages ML and AI tools to improve COVID-19 data collection and analysis and forecasting, as well as vaccine access and distribution.

Examples of activities at agencies outside of HHS with health implications

- Department of Veterans Affairs (VA) National AI Intelligence Institute (NAII): Founded in 2019, the NAII places staff experienced in AI across VA medical centers (VAMCs) and offices nationwide, with the goal of leveraging AI to improve veteran care. Since its inception, the NAII has launched 15-20 pilot projects.
- Department of Justice (DOJ) probe of AI tools: Justice Department investigators are scrutinizing the health care industry's use of AI embedded in patient EHRs that prompts doctors to recommend treatments. From 2018 to 2023, at least three publicly traded pharmaceutical companies disclosed that the DOJ had served them with subpoenas related to electronic medical records.
- DOJ ANPRM on preventing foreign adversaries from accessing data: On March 4, 2024, the DOJ posted an advanced notice of proposed rulemaking (ANPRM) on preventing foreign adversaries from accessing personal and government data – including personal health data. The ANPRM was instructed by a Biden executive order that targets the role of data brokers and highlights AI-related threats such as AI-powered cyber attacks and hostile powers' use of Americans' data to advance their use of the technology.
- Federal Trade Commission (FTC) examination of AI investments and partnerships: On January 25, 2024, the FTC announced that it had issued orders to five companies requiring them to provide information regarding recent investments and partnerships involving GenAI companies and major cloud service providers. The FTC said its goal was to "scrutinize corporate partnerships and investments with AI providers to build a better internal understanding of these relationships and their impact on the competitive landscape."

HHS internal use cases

In addition to incorporating AI into their rulemaking and guidance, HHS and other agencies have started to leverage AI to improve their own operations.

A GAO report reviewing implementation of AI at major federal agencies found that 20 of 23 agencies reported about 1,200 current and planned AI use cases, with HHS reporting 87 in 2022 – behind only NASA and the Departments of Commerce and Energy.

Examples of health agencies' use of AI:

- An HHS AI chatbot that provides an automated email response for general physical security questions, freeing up help desk resources to better assist employees and contractors
- An FDA AI platform trained on 1,500 clinical trials that writes clinical study reports
- An NIH tool to predict priority and research area for grant applications that ranks incoming submissions
- CDC's use of AI and machine learning to improve surveillance testing (e.g., to detect tuberculosis in chest X-rays)

Key questions for policymakers as they consider AI oversight and policy

Statutory authority: What additional statutory authority is needed, if any, to adequately regulate AI in the future?

Definitions: Are AI and AI-associated technologies defined correctly and consistently? How can we regulate and define them in a way that does not preempt future innovation?

Legal implications: What are the legal and/or medical malpractice implications for providers, payers, health tech and others creating and using AI?

Medicare/Medicaid controls: Is there a need to strengthen Medicare and/or Medicaid controls, Conditions for Participation (CoPs) and/or quality program metrics regarding the use and adoption of AI?

Data privacy and nondiscrimination: How can regulation maintain an appropriate balance between data sharing and protection of individual patient data privacy? Are expansions and/or additional clarifications needed under HIPAA, nondiscrimination laws, and/or other patient protection laws? Should patients be able to opt in or opt out of participating in research with de-identified data, and how should the risk of re-identification be addressed?

Reimbursement and approvals: What is the appropriate regulatory framework for approvals and reimbursement of AI-enabled tools and technologies (e.g., for CMS)? What is the best way forward to ensure continued innovation and appropriate, equitable adoption?

Quality, safety and validity: How will quality, safety, and validity be measured? What is the benchmark for success? E.g., if technologies err, but at similar rates as providers or precursor technologies, is that good enough? Is additional standardization needed for "red teaming" or other safety practices?

Standards, assessments and certification: How should standards and/or third-party assessments be prioritized and developed in coordination with the private sector? Should there be a separate AI certification and/or validation process? Should this be done by federal agencies, public-private assurance labs, or others?

Human oversight: What level of human oversight is required for different applications? How will "meaningful" clinical and/or human review and ongoing oversight of AI tools be defined or determined?

Innovation and size: How can we balance responsible use and appropriate guardrails with promotion of innovation and removal of barriers to entry for smaller firms? Will regulations change based on the size of the model and/or company?

Audits and transparency: How should systems be audited and on what frequency to comply with regulations? What level of transparency is necessary, and who should have access?

Bias: If data leveraged by AI is inherently and inappropriately biased and/or unrepresentative, how might regulation prevent and address biased outputs? How will such outputs be detected and escalated?

Infrastructure and training: What infrastructure and training investments are needed to support appropriate and equitable adoption of AI tools?

Next-generation AI: The complexity of regulating next-generation AI, which is based on other AI, will involve assessing a matrix of data that is being input into a prediction model. How will regulation, certification and change management adapt in this context?

4

Defining AI

One size does not fit all

Neither the scientific community nor the industries developing AI technology agree on a common definition of AI.

Similarly, across the government, AI definitions vary (see Table 1). As Saif Khan, Senior Advisor to the Secretary for Critical and Emerging Technologies at the Department of Commerce, told the House Energy and Commerce Committee, AI is a quickly advancing technology.

> “What we call AI today may not be what we call AI tomorrow.
>
> Saif Khan, Senior Advisor to the Secretary for Critical and Emerging Technologies at the Department of Commerce

Table 1: Different AI definitions within the federal government

Source	Definition of AI
President Biden's Executive Order[13]	A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations or decisions influencing real or virtual environments
GAO[14]	Computing systems that "learn" how to improve their performance
HHS[15]	Enables computer systems to perform tasks normally requiring human intelligence
FDA[16]	A branch of computer science, statistics and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions and making predictions
NIST[17]	A branch of computer science devoted to developing data processing systems that perform functions normally associated with human intelligence, such as reasoning, learning and self-improvement. The capability of a device to perform functions that are normally associated with human intelligence such as reasoning, learning and self-improvement.

Other terms that encompass AI and/or AI-related technology (non-exhaustive)	
Advanced analytics	A broad category that includes AI, predictive analytics, ML, deep learning and other computer science methods used to analyze data and/or predict outcomes.
Narrow AI	Specialized AI tools that are trained to do a specific task, such as predict the risk of a cardiac event in a patient, and generative AI, which are more flexible and can understand context and adapt to new situations
Deep learning	A field of AI and computer science, also referred to as self-learning, that uses a variety of algorithms to process and analyze data to generate an output. The field includes large language models, which are commonly used in generative AI, that rely on large datasets to recognize, summarize, translate, predict and generate content.
Machine learning (ML)	A field of AI and computer science that uses advanced statistical methods to identify patterns in data to imitate the way that humans learn, gradually improving its accuracy
Natural language processing (NLP)	A field of AI and computer science that trains algorithms to understand written text and spoken words similar to humans
Large language model (LLM)	A type of AI that are deep learning algorithms that can perform NLP tasks.
Predictive decision support interventions	A broad category adopted by HHS' Office of National Coordinator for Health IT that includes technology — such as AI, ML, natural language processing, and large language models — intended to support decision-making based on algorithms or models that derive relationships from training or example data and then are used to produce an output or outputs related to, but not limited to, prediction, classification, recommendation, evaluation or analysis.

5

Legislative activity

A learning curve

Lawmakers have begun taking the first steps on AI legislation, aiming to promote continued innovation while guarding against potential threats and the risk of overregulating.

Majority Leader Chuck Schumer's (D-NY) bipartisan working group on AI, co-led by Sens. Mike Rounds (R-SD), Todd Young (R-IN) and Martin Heinrich (D-NM), hosted AI Insight Forums last fall and in May, released a "bipartisan road map" for AI policy intended to help jump-start committee activity on AI legislation. Policy priorities highlighted in the road map include increasing funding for AI innovation to propel US leadership; developing new standards for testing and requirements for transparency and explainability; bolstering national security through adoption of emerging technologies; addressing challenges posed by deepfakes and examining the impact on content creators; identifying ways to ensure companies of all sizes can compete; and establishing a strong comprehensive federal data privacy framework.

Other groups are also advancing their own efforts to guide AI policy. Last September, Senate HELP Ranking Member Bill Cassidy (R-LA) released a white paper on AI and its potential benefits and risks to society. In February, House Speaker Mike Johnson (R-LA) and House Minority Leader Hakeem Jeffries (D-NY) appointed 24 House members to a bipartisan task force on AI, "to produce a comprehensive report that will include guiding principles, forward-looking recommendations and bipartisan policy proposals developed in consultation with committees of jurisdiction." Also in February 2024, the Congressional Black Caucus launched an AI Policy Series focusing on AI's potential to discriminate against marginalized Black communities. And in May, the New Democrat Coalition released a list of its priority AI proposals.

While there have been AI-related legislative proposals and quite a few committee hearings in the 118th Congress, there have been few markups on bills that could gain traction. Some key areas of concern raised in health-care-focused legislative proposals have included the use of AI to deny medically necessary claims, the need for a "human in the loop" when AI tools are used for clinical decision-making and medical necessity determinations and creating adequate and consistent reimbursement processes in the future. Congress has also expressed concern that "entrenched inequities and biased data may be baked into algorithms, further exacerbating health disparities and preventing under-resourced providers from accessing AI-enabled technologies."[18] These and other areas are expected to be a continued focus of congressional action and inquiry.

At the same time, there is excitement and interest among policymakers and stakeholders alike in the potential use of AI to mitigate workforce shortages and alleviate clinician burnout, as well as to support clinical decisions and help speed the drug development process, among other potential uses.

There are dozens of proposed pieces of AI legislation currently in various stages of the congressional legislative process, and more are expected to be put forth in the coming weeks and months. Several committee leaders with health care jurisdiction, however, stress that advancing comprehensive data privacy legislation is the most critical first step. In a House Energy and Commerce Committee hearing on AI in December 2023, Chair Cathy McMorris Rodgers (R-WA) said that "we should start with one key action, and that's to lay the groundwork to protect people's information with a national data privacy standard" – a sentiment Ranking Member Frank Pallone (D-NJ) echoed.[19]

In March, Congress approved an appropriations package that included funding for the AI Safety Institute, housed at NIST, which "aims to unite AI creators and users, academics, government and industry researchers, and civil society organizations in support of the development and deployment of safe and trustworthy AI." Various congressional committees have also started to advance certain targeted AI bills, such as the Federal AI Governance and Transparency Act (HR 7532), which would require government contractors to publicly disclose how federal AI systems are developed and maintained (House Oversight and Accountability Committee) and the Protecting Americans' Data from Foreign Adversaries Act of 2024 (H.R. 7520) (House Energy and Commerce Committee) aimed at limiting the amount of sensitive data accessible to foreign adversaries, both of which also advanced in early March. In July, the Senate Commerce, Science and Transportation Committee passed a package of bills on a bipartisan basis, addressing a range of concerns and priorities on AI such as US leadership, regulation, standards and accountability, innovation and R&D, and consumer protection. The Senate Homeland Security Committee also approved the PREPARED for AI Act (S. 4495), a bill that would codify White House procurement guidelines for agencies on purchasing safe and secure AI.

Key enacted AI legislation to date:

The AI in Government Act of 2020 was enacted on December 27, 2020, as part of the Consolidated Appropriations Act of 2021. The law aims to ensure the use of AI across the federal government is "effective, ethical, and accountable" by providing resources and guidance to federal agencies.

The National AI Initiative Act of 2020 was enacted on January 1, 2021, as part of the National Defense Authorization Act for FY 2021. The law established the National AI Initiative Office under the Office of Science and Technology Policy to coordinate federal AI R&D activities and outreach with private sector, academia and other stakeholders.

The AI Training Act was enacted on October 17, 2022, tasking OMB with establishing an AI training program for federal employees, including those at HHS.

Congress has indicated it plans to continue researching AI. While it's unlikely the near-term result will be comprehensive legislation comparable to Europe's Artificial Intelligence Act, we should expect to see continued US legislative activity and efforts to encourage the Administration to use existing authorities to ensure compliance and US leadership in the AI space.

Examples of health care-related AI bills introduced in the 118th Congress (non-comprehensive):

Issue	Bill	Description
Medicare oversight	Medicare Transaction Fraud Prevention Act (S. 3630, H.R. 7147)	Establishes a pilot program for testing the use of a predictive risk-scoring algorithm to provide oversight of payments for durable medical equipment and clinical diagnostic laboratory tests under the Medicare program
Prescribing	Healthy Technology Act of 2023 (H.R. 206)	Establishes that AI or ML technology can qualify as a practitioner eligible to prescribe drugs if authorized by the state involved and authorized by the FDA
Public health response	Artificial Intelligence and Biosecurity Risk Assessment Act (S. 2399, H.R. 4704)	Requires the Assistant Secretary for Preparedness and Response to conduct risk assessments and implement strategic initiatives or activities to address threats to public health and national security due to technical advancements in AI or other emerging technology
	Strategy for Public Health Preparedness and Response to Artificial Intelligence Threats (S. 2346)	Requires the Secretary of HHS to develop a strategy for public health preparedness and response to AI threats, and for other purposes
Research	HEALTH AI Act (H.R. 7381)	Directs the Director of the NIH to establish a grant program to facilitate research regarding the use of generative AI in health care, and for other purposes
Transparency	Health Care Prices Revealed and Information to Consumers Explained Transparency Act (S. 3548)	Amends hospital and insurer price transparency requirements to require, among other items, additional transparency around charges that are based on algorithms

Examples of other AI bills introduced in the 118th Congress with cross-industry implications (non-comprehensive):

Issue	Bill	Description
AI governance and US leadership	Global Technology Leadership Act (S. 1873)	Establishes an executive branch office that would produce an annual assessment to promote US leadership on AI and emerging technologies
	National AI Commission Act (H.R. 4223)	Establishes a national AI commission
	ASSESS AI Act (S. 1356)	Directs the President to appoint a task force to assess the privacy, civil rights, and civil liberty implications of AI, including an HHS designee
	CLOUD AI Act (H.R. 4683)	Prevents China from remotely accessing American semiconductors and chips that it cannot purchase directly under Department of Commerce export controls
	Promoting United States Leadership in Standards Act of 2024 (S. 3849)	Directs NIST and the Department of State to take certain actions to encourage and enable US participation in developing standards and specifications for AI and other critical and emerging technologies
AI use in federal agencies	Federal AI Governance and Transparency Act (H.R. 7532)	Requires government contractors to publicly disclose how federal AI systems are developed and maintained
	TAG Act (S. 1865, H.R. 6886)	Requires federal agencies to be transparent when using automated and augmented systems to interact with the public or make critical decisions
	Federal Artificial Intelligence Risk Management Act of 2023/2024 (S. 3205, H.R. 6936)	Directs federal agencies to use NIST's AI Risk Management Framework and for NIST to issue agency-specific guidelines for AI risk management
	AI Leadership Training Act (S. 1564)	Requires the Director of the Office of Personnel Management to establish an AI training program for federal management officials and supervisors
	AI Training Expansion Act of 2023 (H.R. 4503)	Expands AI training for federal workers
	AI LEAD Act (S. 2293)	Establishes the Chief AI Officers Council, Chief AI Officers, and AI Governance Boards across federal government agencies to govern the use of AI
	AI Consent Act (S. 3975)	Requires companies to receive consent from consumers to having their data used to train an AI system
Foreign adversaries use of data	Protecting Americans' Data from Foreign Adversaries Act of 2024 (H.R. 7520)	Bans companies from licensing, selling, or otherwise making available the sensitive data of US residents to foreign adversaries, or companies controlled by foreign adversaries
	Protecting Americans from Foreign Adversary Controlled Applications Act (H.R. 7521)	Prohibits distributing, maintaining or providing internet hosting services for a foreign adversary-controlled application

Generative AI	AI Labeling Act (H.R. 6466, S. 2691)	Requires generative AI outputs to include a clear and conspicuous disclosure identifying the content as AI-generated
	Advisory for AI-Generated Content Act (S. 2765)	Requires a watermark for AI-generated materials and provides enforcement authority to the FTC
	AI Disclosure Act of 2023 (H.R. 3831)	Requires generative AI output to include a disclaimer stating, "this output has been generated by artificial intelligence"
	Do Not Disturb Act (H.R. 7116)	Strengthens certain provisions relating to restrictions on robocalls and telemarketing
	QUIET Act (H.R. 7123)	Requires disclosures with respect to robocalls using AI and provides for enhanced penalties for certain violations involving AI voice or text message impersonation
	R U REAL Act (H.R. 7120)	Directs the FTC to revise the Telemarketing Sales Rule to require disclosures for telemarketing using AI and to provide for enhanced penalties for violations involving AI voice or text message impersonation
	Generative AI Copyright Disclosure Act of 2024 (H.R. 7913)	Requires a notice be submitted to the Register of Copyrights with respect to copyrighted works used in building generative AI systems
	Protecting Consumers from Deceptive AI Act (H.R. 7766)	Requires NIST to establish task forces to facilitate and inform the development of technical standards and guidelines relating to the identification of content created by generative AI, to ensure created content includes a disclosure acknowledging the origin
Research and innovation	Artificial Intelligence Research, Innovation, and Accountability Act of 2023 (S. 3312)	Creates a framework to bolster innovation and bring greater transparency, accountability, and security to the development and operation of the highest-impact applications of AI
	CREATE AI Act of 2023 (H.R. 5077, S. 2714)	Creates a national research center to enhance access to AI resources for underrepresented researchers
	Ensuring Safe and Ethical AI Development Through SAFE AI Research Grants (H.R. 6088)	Directs the National Academy of Sciences to establish a grant program to encourage the development of safe AI models and safe AI research
	TEST AI Act of 2023 (S. 3162)	Strengthens the requirement for NIST to establish testbeds for AI
	AI Grand Challenges Act of 2024 (S. 4236)	Authorizes the Director of the NSF to identify grand challenges and award competitive prizes for AI research and development across several categories, including health care

Safety, bias and equity	Algorithmic Accountability Act of 2023 (S. 2892, H.R. 5628)	Directs the FTC to require companies to conduct impact assessments for effectiveness, bias and other factors when using automated decision systems and augmented critical decision processes to make critical decisions
	Eliminating Bias in Algorithmic Systems Act of 2023 (S. 3478)	Requires agencies that use, fund, or oversee algorithms to have an office of civil rights focused on bias, discrimination, and other harms of algorithms, and for other purposes
	Artificial Intelligence Literacy Act of 2023 (H.R. 6791)	Amends the Digital Equity Act of 2021 to facilitate AI literacy opportunities, and for other purposes
Standards and metrics	AI Foundational Model Transparency Act of 2023 (H.R. 6881)	Directs the FTC to establish standards for making information about the training data and algorithms used in AI foundation models publicly available
	Future of Artificial Intelligence Innovation Act of 2024 (S. 4178)	Establishes AI standards, metrics, and evaluation tools, to support AI research, development, and capacity-building activities so companies of all sizes can succeed and thrive
Studies	Consumer Safety Technology Act (H.R. 4814)	Directs the Consumer Product Safety Commission to establish a pilot program to explore the use of AI in support of the mission of the Commission and directs the Secretary of Commerce and the FTC to study and report on the use of blockchain technology and digital tokens, respectively
	Artificial Intelligence Accountability Act (H.R. 3369)	Directs the Assistant Secretary of Commerce for Communications and Information to conduct a study and hold public meetings with respect to AI systems
Workforce	Technology Workforce Framework Act of 2024 (S. 3792)	Expands the functions of NIST to include workforce frameworks for critical and emerging technologies, requires the Director of NIST to develop an AI workforce framework, and to periodically review and update the National Initiative for Cybersecurity Education Workforce Framework for Cybersecurity

6

What's next

AI development and adoption is moving rapidly, necessitating acceleration on the legislative and regulatory front.

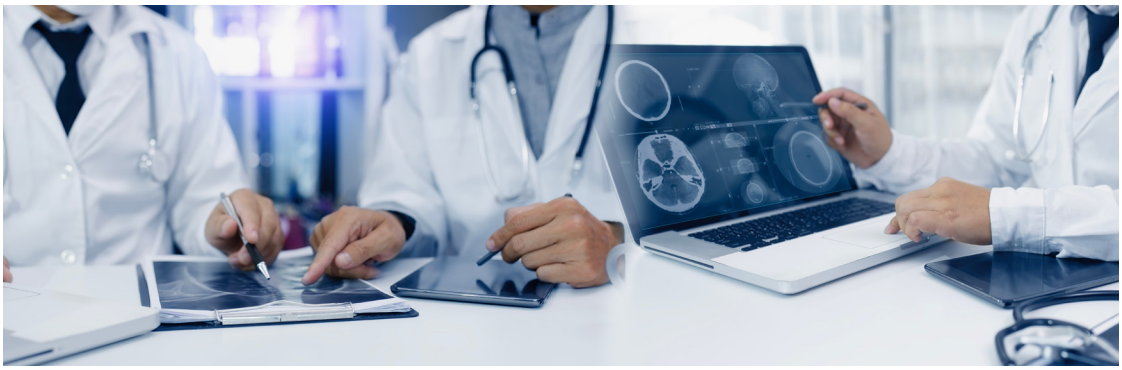
We expect many proposals will seek to provide industry with guidance and guardrails so that innovators can develop innovative technologies with confidence, providers and payers can responsibly adopt these technologies, and the health care system, as well as its various stakeholders, can experience improved outcomes and fewer potential harms and burdens.

Policymakers seem to understand this imperative. AI will continue to be a key consideration in rulemaking and legislation, discussions and hearings on Capitol Hill and across agencies, and in political dialogue. The Administration is also expected to flex its enforcement authorities under the FTC, DOJ and HHS to address uses of AI that impact patient and consumer data privacy, and to provide data protection and data sharing practices, along with other consumer protections. FTC Chair Lina Khan has said that AI tools will be "vigorously regulated with an eye on consumer privacy."[20]

In addition to the federal focus on AI policymaking, state legislators have also been working to implement state-specific AI guidance, which has resulted in a growing patchwork of state regulations. Since 2019, 17 states have enacted 29 bills focused on regulating the design, development and use of AI — with more expected to come in 2024.[21] Globally, efforts are advancing to develop common AI ethics and governance principles, including those by the World Health Organization. At the same time, individual countries and regions are advancing their own efforts, most notably the landmark EU Artificial Intelligence Act. Countries have passed 123 AI-related bills globally since 2016; the majority of these laws have been passed in recent years.[22] Here in the US, there is likely to be a continued focus from the Administration on international collaboration to accelerate the learning curve and increase the chances of alignment.

Industry will continue to be a key player and partner in the quest to establish guidelines around responsible use of AI. In the health care space, some stakeholders are developing their own AI standards. Groups like the Coalition for Health AI (CHAI) and industry leaders such as the Johns Hopkins Applied Physics Laboratory have released frameworks for responsible AI in which they detail areas that they think require regulatory attention.[23] CHAI also recently announced a public-private

partnership with federal partners including the White House, HHS, FDA and VA to develop a testing and evaluation framework for generative AI. By the third quarter of 2024, CHAI aims to support a network of assurance labs to validate and monitor AI that will likely be housed in major universities nationwide. Industry is also moving to self-regulate, with a growing number of companies providing services that evaluate whether their AI models are complying with local regulations, adhering to representations made to purchasers and/or following existing "responsible AI" or similar standards.



As AI's capabilities have continued to evolve and expand, the number of stakeholders that want a say in the development of guidelines regulating the technology has also increased.

Even with this ever-growing list of interested parties, it is clear that Washington views itself as holding a key role in promoting AI innovation and protecting individual rights, while also promulgating fair and administrable rules. What the final outcome will be remains to be seen as Washington moves past voluntary regulatory standards and toward legislative requirements. The stakes for AI are especially high in the deeply personal realm of health care, where AI may present both serious risks and life-changing potential.

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