



Biden Issues Executive Order on Artificial Intelligence

On October 30, 2023, President Joseph Biden signed an executive order to establish new standards for artificial intelligence (AI) in the U.S.¹ The executive order focuses on protecting the privacy of Americans and establishes new standards for security and safety in AI.² While the executive order is not specific to healthcare, the order contains some healthcare-specific provisions. This Health Capital Topics article will discuss the executive rule, subsequent agency actions, and industry implications.

The executive order is guided by eight priorities and principles:

- (1) “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) “The US should promote responsible innovation, competition and collaboration via investments in education, training, [research & development] and capacity while addressing intellectual property rights questions and stopping unlawful collusion and monopoly over key assets and technologies”;
- (3) “The responsible development and use of AI require a commitment to supporting American workers through education and job training and understanding the impact of AI on the labor force and workers’ rights”;
- (4) “AI policies must be consistent with the advancement of equity and civil rights”;
- (5) “The interests of Americans who increasingly use, interact with, or purchase AI and AI-enabled products in their daily lives must be protected”;
- (6) “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) “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) “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.”³

While the executive order impacts a variety of industries, there are many implications for the healthcare industry specifically. The order directs the Department of Health and Human Services (HHS) to develop a task force focused on AI within 90 days, which task force will be responsible for developing frameworks and policies on the responsible use and deployment of AI and AI-enabled technology.⁴ Within 365 days of the task force’s creation, new guidance must be created related to the monitoring of quality and safety of technology enabled by AI and the incorporation of equity in new AI models.⁵

Additionally, HHS is tasked with establishing a safety program that is capable of receiving reports, which will ultimately guide the agency in remedying unsafe practices in healthcare settings that involve the use of AI.⁶ HHS is also expected to take appropriate actions to ensure compliance with federal nondiscrimination law.⁷ The agency will be given 180 days to decide if the current AI applications are sufficiently accurate for use in the healthcare industry.⁸ HHS will also work alongside the Department of Defense (DOD) and the Department of Veterans Affairs (VA) to develop and establish frameworks that can capture and identify clinical errors in all healthcare settings that may result from AI use.⁹ The administration is also expected to increase funding for grants in AI research.¹⁰

In addition to the federal government’s push to monitor and regulate AI, the rapid implementation of the technology requires healthcare organizations to monitor any risks (e.g., reputational, legal, and ethical) emanating from AI use and determine how to address those risks, particularly given the current lack of regulatory framework and oversight.¹¹ Toward that end, and in the absence (to date) of governmental the American Medical Association (AMA) voted in June 2023 to adopt a proposal to protect patients against misleading or false medical information from AI tools.¹² The AMA aims to work with agencies such as the Federal Trade Commission (FTC) and the Food & Drug Administration (FDA) to mitigate any misinformation, and anticipates the establishment of federal and state regulations in the near future.¹³

Even before the issuance of the executive order, AI companies had already started to face government scrutiny. In July 2023, the FTC opened an investigation and sent a records request to OpenAI, the company behind ChatGPT, a free-to-use generative AI bot.¹⁴ In its investigation as to whether OpenAI engaged in practices that resulted in consumer harm, the FTC requested information regarding how OpenAI obtained data used to train their models and descriptions of ChatGPT's abilities.¹⁵ The agency also requested descriptions of OpenAI's testing, algorithms, responses, and the company's false information policies.¹⁶

The level of development and the pace of clinical AI implementation may be directly influenced by the liability faced by practitioners, designers, and health systems, as more liability could discourage the use of AI

in healthcare.¹⁷ As the technology continues to be developed and utilized, new legal pathways will need to be established, especially as increased liability would likely repel practitioners, designers, and health systems from implementing and developing clinical AI models.¹⁸

While the executive order directs federal agencies to coordinate efforts around the regulation of AI, the agencies can only act within their budget and authority.¹⁹ Another impediment to AI regulation may include any change in presidential administration, where different priorities may result in the executive order being revoked.²⁰ While many of the executive order's provisions have bipartisan support, the implementation of the policies may not be completed before the 2024 Presidential Election, leaving the ultimate outcome of these policies vulnerable to changing political forces.²¹

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