

AI and Healthcare: More Guidance and Regulations are Coming to Town

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by Rebecca A. Brommel

There is no doubt that artificial intelligence (“AI”) and more specifically, generative AI, is one of the hottest topics in healthcare for 2023. There is also no doubt that it will continue to be a hot topic into 2024 and beyond as healthcare providers and patients have greater access to generative AI and learn how to use it within the world of healthcare.

On October 30, 2023, the Biden Administration took another step toward addressing AI by issuing an *Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence* (available [here](#)). The Executive Order follows an October 2022 blueprint for an AI Bill of Rights, which was intended to outline principles “that should guide the design, use, and deployment of automated systems to protect the American public in the age of artificial intelligence.” The AI Bill of Rights Blueprint is available [here](#).

The Executive Order confirms that the Biden Administration recognizes the potential of AI to “solve urgent challenges while making our world more prosperous, productive, innovative, and secure”. However, the Administration also recognizes that “irresponsible use could exacerbate societal harms such as fraud, discrimination, bias, and disinformation; displace and disempower workers, stifle competition; and pose risks to national security.” With these issues in mind, the Executive Order sets forth eight principles:

1. AI must be safe and secure.
2. Promoting responsible innovation, competition and collaboration will allow the United States to lead in AI and unlock its potential to solve some of society’s most difficult challenges.
3. Responsible development and



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use of AI requires a commitment to supporting American workers.

4. AI policies must be consistent with the advancement of equity and civil rights. The Executive Order specifically mentions that healthcare, in particular, is an area where AI can deepen discrimination and bias.
5. The interests of Americans who increasingly use, interact with, or purchase AI and AI-enabled products in daily life must be protected. The Executive Order notes that this is critical in fields such as healthcare.
6. Americans' privacy and civil liberties must be protected.
7. The federal government must manage risks in its own use of AI and increase internal capacity to regulate, govern and support responsible use of AI.
8. The United States federal government should lead the way globally with respect to AI.

Importantly, the Executive Order provides a comprehensive list of AI-related definitions, some of which already exist in federal statutes or regulations, but perhaps have not previously been applied across the various industries such as healthcare.

The Executive Order then provides specific directives and deadlines to various federal agencies to implement the eight principles. With respect to the healthcare sector, the Executive Order directs the Secretary of the Department of Health and Human Services ("HHS") to take the following actions:

- Within 90 days, establish an HHS AI Task Force.
- Within 365 days of being created, the HHS AI Task Force will develop a strategic plan that includes policies and frameworks and possible regulatory actions on responsible deployment and use of AI and AI-enabled technologies in the following areas:
 - Healthcare delivery and financing, and specifically, quality measurements, performance improvement, program integrity, benefits administration and patient experience
 - Safety and performance monitoring of AI-enabled technologies, including clinically relevant or significant modifications and performance across population groups
 - Incorporation of equity principles for AI-enabled technology using disaggregated data and helping to identify and mitigate discrimination and bias in current systems
 - Safety, privacy and security standards for protecting personally identifiable information
 - Development, maintenance and availability of documentation to help users determine safe and appropriate uses of AI in local settings
 - Determine work to be done with state, local, Tribal and territorial health and human service agencies to advance positive uses cases and best practices
 - Identify uses of AI to promote workplace efficiency, including reduction of administrative burdens
- Within 180 days, develop a strategy with relevant agencies to determine whether AI-enabled technologies maintain appropriate levels of quality, including the development of an "AI assurance policy" that will evaluate important aspects of performance. This includes an infrastructure to enable pre-market assessment and post-market oversight.
- Within 180 days, consider appropriate actions needed to advance understanding and compliance with federal non-discrimination laws by healthcare providers that receive federal financial assistance and how those laws relate to AI.
- Within 365 days, in consultation with other federal agencies, establish an AI safety

program in partnership with voluntary, federally listed Patient Safety Organizations. This directive calls for establishing a common framework for identifying and capturing clinical error resulting from AI and developing best practices or other guidelines to avoid harms.

- Within 365 days, develop a strategy for regulating use of AI or AI-enabled tools in drug-development processes.



Given this more specific framework and the guidance and regulations expected to result from this Executive Order, it is also likely that states and Congress will continue to review and develop legislation around the use of AI generally, and in healthcare in particular. This will likely result in a varying assortment

of regulations that providers, AI developers and others in the healthcare sector will need to understand and address.

AI is here to stay, and healthcare providers will need to be alert to forthcoming laws, regulations and guidance from varying levels of government, as well as from professional organizations. See <https://www.ama-assn.org/press-center/press-releases/ama-develop-recommendations-augmented-intelligence> (providing that the American Medical Association will be developing principles and recommendations on the benefits and unforeseen consequences of relying upon AI-generated medical advice or content).

If you have any questions regarding the current AI regulatory framework or how your organization may be impacted, please contact the author or your Dorsey healthcare attorney.