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The Governance Implications of Biden's AI Executive Order

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President Biden's expansive new Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence (EO) sets forth a framework for federal regulation and oversight of artificial intelligence (AI) for the foreseeable future. As such, it will have a profound impact on how health care boards consider the risks and benefits of AI and machine learning technology, and the organizational hierarchy to manage it.

Background

Issued on October 30, the EO represents the latest and most significant governmental effort (federal or state) to establish a regulatory strategy for responsible AI development, deployment, and use. As described in an accompanying Fact Sheet, the EO "establishes new

standards for AI safety and security" intended to protect the public from potential harm, as well as provisions intended to enhance the promise of AI and catalyze AI research to advance American competitiveness.

The EO builds upon two prior AI oversight initiatives of the Biden administration: the "Blueprint for an AI Bill of Rights" published by the White House Office of Science and Technology Policy in October 2022, and the voluntary commitments from 15 leading companies received by the administration to drive safe, secure, and trustworthy development of AI.

And like the Biden administration's 2021 Executive Order on Promoting Competition in the American Economy, this latest executive order takes a "whole of government" approach to steering AI technology, which the order defines as "a machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments."

While Congress is considering new AI-related legislation (including bills to codify directives in the executive order), the administration intends to pursue the EO's directives through policy guidance, federal rulemaking, and other actions initiated by federal agencies, such as the Department of Commerce, the Department of Homeland Security, the National Security Agency, the Department of Justice, the Department of Health and Human Services (HHS), and the Federal Trade Commission.

As the health industry knows well from an antitrust enforcement perspective, such a "whole of government" approach can have a significant impact on their operations and strategies.

The breadth of the EO and its specific provisions regarding the use of AI in health care and life sciences underscore the need for health care boards to orient their oversight and decision-making processes to align with the order's guiding principles, focusing on the safe, secure, and ethical use of AI.

Overview of Health Relevant Directives in the Executive Order

The EO is a massive document, both in size (20,000+ words) and scope. It includes several directives aimed at HHS that will have significant impacts on the health care industry, including the following HHS-specific requirements:

- Create an HHS AI Task Force within 90 days of the EO that must develop a strategic plan on the responsible deployment and use of AI and AI-enabled technologies in the health and human services sector (including research and discovery, drug and device safety, health care delivery and financing, and public health) within one year.

The strategic plan could include policies, frameworks, and regulatory action (as appropriate) and should promote:

o Developing, maintaining, and using predictive and generative AI-enabled technologies in health care delivery and financing;

o Long-term safety and real-world performance monitoring of AI-enabled technologies in the health and human services;

o Incorporating equity principles into AI-enabled technologies used in the health and human services;

o Incorporating safety, privacy, and security standards into the software-development lifecycle for protection of personally identifiable information; and

o Creation of documentation to help health and human services users determine appropriate and safe uses of AI.

- Create an HHS strategy to "determine whether AI-enabled technologies in the health and human services sector maintain appropriate levels of quality" within 180 days of the EO, including developing an AI assurance policy to evaluate important aspects AI-enabled health care tools' performance.
- Take steps to advance compliance with federal nondiscrimination laws by "health and human service providers" that use AI and receive federal financial assistance within 180 days of the EO.
- Establish an HHS AI safety program to work in partnership with Patient Safety Organizations within 365 days of the EO, acting in consultation with the Department of Defense and the Secretary of Veterans Affairs, and specifically requiring the establishment of a "common framework for approaches to identifying and capturing clinical errors resulting from AI deployed in healthcare settings as well as specifications for a central tracking repository for associated incidents that cause harm, including through bias or discrimination, to patients, caregivers, or other parties."
- Develop an HHS strategy for regulating the use of AI or AI-enabled tools in drug-development processes (including clinical trial and post-market surveillance and monitoring phases).

These HHS-specific directives are just a few of the EO's numerous and far-ranging instructions for various federal agencies and other executive officials. Future material developments to advance the EO's directives will come directly from federal agencies, such as HHS, and will likely come quickly. It is critical for health care organizations to take this time to proactively shape and prepare their AI governance frameworks and processes consistent with the guiding principles in the EO and in anticipation of new responsible AI

standards. Health care organizations should also be ready for engagement opportunities to shape AI policy and standards through new task forces established through the EO.

What It Means to Boards

The health care board's role with respect to AI arises from multiple levels of operation that have material strategic and tactical implications to the company, including but not limited to (i) the role of AI in "mission critical activities" such as the delivery of care; (ii) critical operational functions such as risk management, corporate compliance, cybersecurity, privacy; and (iii) how AI related "trust" issues may impact the reputation of the company (a significant corporate asset which the board is expected to preserve).

As a result, several provisions of the EO (especially those that might result in new safety standards and reporting requirements) should draw specific board interest and confirm the overall need for the board to formalize its AI related oversight and decision-making protocols. Based on the principles and priorities set out in the EO, the board's AI oversight might include active monitoring of: the development and implementation of AI safety programs, opportunities to engage with regulatory and policy changes, and compliance programs to ensure that AI technologies are deployed consistent with new and evolving federal and industry guidelines. It's a multifaceted challenge that requires a nuanced balancing of both the transformative potential of AI and the emerging ethical, legal, and regulatory frameworks that will establish guardrails for its use.

The EO should serve as an alert to health care boards that forthcoming regulation and guidance will impact their oversight and fiduciary responsibilities. More specifically, the EO should alert boards to the ways in which they should be engaging with executive leadership to develop the administrative infrastructure that will address regulatory and policy changes stemming from the EO's directives. This will most certainly include, but will not be limited to, expanding the AI related responsibilities of the chief legal officer and the chief compliance officer, and improving horizontal and vertical information reporting systems on AI related risks and opportunities.

The NACD's Recommendation

Serendipitously with the release of the EO is the recent recommendation from the National Association of Corporate Directors (NACD) regarding the formation of a board-level science, technology, and innovation-styled committee, whose charter could be framed to coordinate oversight for technology-oriented operational programs, investments, and risks. Such a committee could also serve to monitor technology related developments, trends, and emerging capabilities. In addition, this committee might be an efficient means through which the board could monitor AI and other emerging technology matters, perhaps in

coordination with committees such as Audit & Compliance and Strategic Planning, that have similar connections to the topic.

Conclusion

The Biden administration's new Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence is a major step forward in the federal government's effort to exercise oversight on AI development and use. It is of particular interest to the health care industry given specific health care-related directives and the promise of health AI applications. Moreover, the EO's recognition of the duality of AI advancements—their yet to be unlocked potential and their yet to be understood perils—serve as a reminder to health care corporate boards of the need to assert a specific role for governance in the safe, secure, and trustworthy development, acquisition, and use of AI.

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