

## 'Devil's In The Details' Of Biden's AI Health Plans, Experts Say

By **Gianna Ferrarin**

*Law360 (November 3, 2023, 10:40 PM EDT)* -- BigLaw experts have praised President Joe Biden's sweeping plan to harness the powers of artificial intelligence to develop potent cancer treatments, improve equity in the medical field and otherwise serve patients and heal the ills of the U.S. health care industry.

But many are also keen to see how the administration's ambitious plans will be implemented across all levels of government, and better understand the potential application of AI guardrails in areas such as patient privacy and algorithmic bias.

"Health care is so regulated, with Medicare, Medicaid, the FDA processes — there are processes that are already in place," said Rachel Snyder Good, a health care strategic counsel at Epstein Becker Green. "And so we need to make sure that we're being clear on where there is regulation needed and where there is legislation needed."

As part of a landmark directive that promises to touch virtually every major industry, the Biden administration in recent days tasked the U.S. Department of Health and Human Services with developing policies on the use of artificial intelligence in clinical care, drug development and other areas of the health sector.

The overarching goal of creating guardrails and opportunities for AI innovation has special resonance for health care in America, holding the potential to improve the effectiveness of cancer drugs, to cite just one example, even as many see threats to the privacy of patients' personal information, among other deep concerns.

The 100-page order directs HHS to examine these potential harms and benefits, including by addressing unjust denials of federal health benefits. The agency was also ordered to support the development of AI tools that create "personalized immune-response profiles" for patients.

Under the order, which Biden signed Oct. 30, HHS will have roughly three months to create a task force responsible for developing a strategic AI plan.

Once formed, that group will then have 365 days to develop a strategic plan outlining policies and frameworks on the responsible deployment of AI in health care delivery and financing, drug and device safety, and public health.

HHS must also craft guidance on building privacy standards into the software development cycle, safety and performance monitoring of AI technologies, and the uses of AI to reduce administrative burdens in the health sector.

"I think having this oversight and making sure that these safeguards are in place without crushing innovation is just the key to making AI work, elsewhere but particularly in health care," said Good.

Jodi Daniel, a health care partner at Crowell & Moring LLP, said she was eager to see what comes out of the HHS AI task force in light of the myriad potential applications of predictive AI in health care, from delivery of health services to safety improvements and issues of equity.

The order "was quite broad, and I am hoping that the strategic plan provides more clarity on the areas that HHS feels are most important," Daniel told Law360.

Daniel, who served as the head of health information technology policy for HHS for a decade and helped draft the Health Insurance Portability and Accountability Act, pointed out the vast amount of data required to develop AI and highlighted opportunities for the task force to expand privacy protections.

"I would suspect that the task force will look at the HIPAA regulations and either incorporate some guidance about how privacy and security standards apply to testing of AI models or development of AI technology and the use of information for that purpose, or propose changes to regulation to enhance privacy protection," Daniel said.

The order also seeks to expand reporting of incidents of harm from the deployment of AI in health care settings, such as discrimination and bias against patients and caregivers. Under a 365-day deadline, HHS will create a safety program that establishes specifications for a "central tracking repository" of such incidents and disseminate best practices to health care providers.

Daniel said this proposed safety program may expand and improve on current systems of mandated reporting. While the U.S. Food and Drug Administration defines certain artificial intelligence and machine learning-based software as a medical device — and can thus receive reports of harms through its adverse event reporting system — Daniel said the proposed AI program may go beyond that system.

"Presumably, this is broader because there are technologies and software that may incorporate AI that may be outside of FDA scope," Daniel said. "So, obviously, devil's in the details, really want to see more on what it typically says on that or how that's interpreted, but I think that's particularly interesting from the health care perspective."

The Biden administration has also tasked HHS with examining how health care and public benefits providers will be impacted by AI, giving the agency roughly six months to examine how AI intersects with federal nondiscrimination laws governing health providers that receive federal financial assistance. HHS will also have 180 days to develop an AI assurance policy and publish a plan on the use of algorithmic systems in the administration of public benefits by states and localities.

That plan may promote an assessment of access to benefits, evaluation to detect unjust denials and processes to appeal denials to human reviewers, according to the order.

According to the order, HHS also has 365 days to develop a strategy for regulating the use of AI in the drug development process, including defining objectives for the regulation of different phases of drug

development and identifying where additional statutory authority may be needed to regulate this process.

"These tight turnaround times — I was glad to see that it was 180 days for this or 365 days for that — means that the government will have compiled all of this great information before the election," said Good. "And no matter who is the next administration, whether it's a continuation of this one or a new administration — this is a bipartisan issue. This is something everybody agrees needs to happen."

In addition to these guardrails, the order outlines opportunities for AI innovation in the health sector. It directs the HHS to advance the development of AI tools for clinical care, population health and research by collaborating with private sector actors and prioritizing grants and awards in that area.

Michael Pencina, who is a member of a coalition of academic health systems and technology companies called the Coalition for Health AI, said he was glad to see references to public-private partnerships in the order. Pencina says the coalition partners with the FDA, Centers for Medicare & Medicaid Services and other federal health agencies.

"It's not possible for the government to do it all," said Pencina, who also serves as the vice dean for data science at the Duke University School of Medicine. "I think we need the government to kind of lead the way and set the path, but truly the enforcement and implementation of what's happening needs to be distributed, right? So I think that mention of public-private partnerships is really, really important in the executive order."

Pencina highlighted applications of AI that he has seen presented at health technology conferences, including technology that can listen to doctor-patient conversations and create clinical notes with "amazing fidelity." He emphasized the importance of ensuring these AI health technologies are truly effective and do not discriminate against patients.

"The potential is incredible, right? We have a huge burden issue with doctors and with nurses, in particular," Pencina said. "So anything that we can do to reduce their burden through technology is very, very welcome."

Good, who previously served as a policy adviser in the House of Representatives for several years, emphasized the need for industry groups to weigh in as government agencies and Congress develop regulations and legislation in response to the order.

"This is a really big step forward," Good said. "But that's all it is — it's the beginning of a process. And I know that people are anxious to know where it's going to go. But I'm glad to see the process starting."

--Editing by Jay Jackson Jr. and Michael Watanabe.