AMA PRESIDENT CRITICIZES FEDERAL EFFORTS TO HOLD DOCTORS LIABLE FOR AI SHORTFALLS

Federal regulatory efforts to hold physicians liable for poor clinical decisions resulting from use of artificial intelligence (AI) have sparked strong protests from the new head of the nation's largest physician lobby, and the top Republican on the Senate health committee says liability questions spurred by the increasing use of algorithms in health care need to be sorted out.

The questions come as stakeholders grapple with how to deal with the increasing prominence of AI and machine learning in health technology.

American Medical Association (AMA) President Jesse Ehrenfeld raised concerns in a recent interview that federal regulators want to hold physicians liable for harms resulting from the use of AI in health care. "We're seeing a recent federal proposal that seeks to hold physicians solely liable for harms resulting from an algorithm if they rely on the output of those algorithms," Ehrenfeld said. "We think that that will be a market killer." "Liability is a potential barrier to the uptake of AI," he continued. "Liability ought to be placed with the people who are best suited to mitigate it. And that may be the developer, it may be the implementer. It often is not going to be the end user. So we need to figure out what happens when something goes wrong, who is liable when there is a problem with the output of an algorithm. And that is a really, really important open question right now."

Ehrenfield was likely referring to a broad update HHS proposed to its nondiscrimination rules in August 2022 but has not yet finalized. The proposed rule makes it clear that HHS considers providers the liable parties when there are discriminatory impacts resulting from the use of artificial intelligence and algorithms.

Sen. Bill Cassidy (R-LA), ranking GOP member on the Senate health committee, is also raising liability questions. Cassidy recently released a white paper on potential benefits and risks of AI that says stakeholders are currently unclear on the legal issue. "Like any medical device, failure of a product that incorporates AI could harm patients, such as through incorrect diagnoses (both false positives and false negatives) ... A predictable framework is needed to facilitate adoption of these tools, which requires determining where liability lies -- the original developer, most recent developer, clinician, or other party," the white paper says. Cassidy did not say where he believes liability should rest or whether legislation on the issue should be introduced.

HHS' proposed rule says that although a covered entity may not have designed a clinical algorithm and may be unaware of its discriminatory impact, it is responsible for ensuring actions it takes based on recommendations provided by an algorithm do not result in discrimination. "The fact that a covered entity did not design the algorithm or does not have knowledge about how the tool works does not alleviate their responsibility to ensure that they do not take actions that result in discrimination," HHS wrote.

The document also says providers must take steps like developing policies and providing training on algorithmic bias to help avoid discriminatory impacts. "While covered entities are not liable for clinical algorithms that they did not develop, they may be held liable under this provision for their decisions made in reliance on clinical algorithms," the proposed rule says. "Covered entities using clinical algorithms in their decision-making should consider clinical algorithms as a tool that supplements their decision-making, rather than as a replacement of their clinical judgment."

It continues, "By over-relying on a clinical algorithm in their decision-making, such as by replacing or substituting their own clinical judgment with a clinical algorithm, a covered entity may risk violating Section 1557 if their decision rests upon or results in discrimination."

Many health care stakeholders have recently taken action to address the increasing role of artificial intelligence and machine learning in the industry. The AMA points readers to the Health AI Partnership, which has created a series of guides for clinicians and other health professionals on AI usage. The guides focus on improving health equity and patient care, improving the clinical work environment, and advancing broad participation in conversations about new technologies.

The White House's AI strategy has not made health care a focus, although two of the companies which joined its safety pledge on the telehealth in July, Google and Amazon, have health care aspects. FDA, CMS and HHS' health IT office have also worked on how to regulate the incorporation of AI in areas such as pharmaceutical and medical device development, prior authorization and telemedicine.