

Insurer Use of AI in Healthcare Draws Expansive Scrutiny

By Robert B. Hille and John W. Kaveney

The concept of artificial intelligence (AI) has permeated almost all aspects of society. AI is being implemented more and more each day by major technology companies to try and improve daily living and optimize the delivery of data and information in our daily lives. AI is also being viewed as a tool that will revolutionize and improve the delivery of healthcare.

On the one hand, providers are using AI as a tool to improve patient care. For example, efforts are being made to utilize AI to improve the diagnosing of patients, analyzing medical images, and predicting patient outcomes to better anticipate complications and best courses of treatment.

On the other hand, insurers are also using AI tools to personalize health services and products, predict future events and potential patient health risks more accurately, and improve the processing and payment of medical claims.

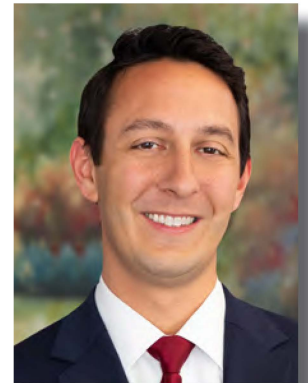
However, while these uses by insurers can have a positive impact on the delivery of care, many in the healthcare industry, and federal government, have raised concerns about other uses of AI by insurers. Specifically, insurers are increasingly utilizing AI to process and evaluate claims absent the human element and the necessary expert review, resulting in concerns that outcomes are being determined solely by algorithms. In such scenarios, individual patient reviews by an experienced and qualified reviewer is taking a back seat to where a case fits within a data population. While patients and patient outcomes may form data, they are not simply data points to be subjected to a formulaic approach. Each case is unique and fluid.

Federal Definition of AI

The federal government has statutorily defined AI 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.” AI systems use machine- and human-based inputs to “perceive real and virtual environments; . . . abstract such perceptions into models through analysis in an automated manner; and . . . use model inference to formulate options for information or action.” These machine- and human-based inputs greatly shape how such a system functions and can lead to potential problems.



Robert B. Hille



John W. Kaveney

Problems with AI use arise with inherent data biases, incomplete or unreliable data and inaccurate or inflexible algorithms that lead to skewed results. Care then is misdirected to the individual based on the population’s rather than the individual’s needs. The resulting care the tool directs is consequently population rather than patient driven.

An analogy would be if a robotic surgical instrument was programmed on the sum total of the surgical patient population rather than to respond to the individual patient’s particular anatomy. Cutting into a patient where an artery should be rather than where it is demonstrates the harm from eliminating individual patient needs from the care rendered.

Federal Concerns Regarding Coverage and Claim Denials

AI’s recent spotlight has been in the Medicare Advantage (MA) arena. There, fears have been raised that AI is being used to enhance improper coverage and claims denials.

Accusations of improper denials by Medicare Advantage Organizations (MAO) are not new. Such abuse has been on the federal government’s radar for several years. Most recently in 2018, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued its report on “Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns About Service and Payment Denials.” There, the OIG found “widespread and persistent problems related to denials of care and payment in Medicare Advantage plans.” The OIG’s report also noted that MA plans “overturned 75 percent of their own denials” while at the same time, “beneficiaries and providers appealed only 1 percent of denials to the first level of appeal.” Largely predating AI use by insurers, the widespread denial errors noted in the report may form, inadvertently or by

design, a biased data population that would skew MAO claims outcomes in favor of denials. This would place greater sums in the pocket of insurers despite them receiving that money based on representations to the government that the money was needed to compensate for the care they later denied.

A June 2022 OIG claims study further substantiated Government fears of abuse. Reviewing a random sample of prior authorization and payment denials by 15 large MAOs in 2019, the OIG found only 13% of coverage denials and only 18% of payment denials met Medicare MA rules. The report also identified the avoidable delays, additional work, and administrative burdens that the inappropriate denials caused that negatively impacted patient care and placed avoidable burdens on providers. Based on its review, the OIG recommended CMS “issue new guidance on the appropriate use of MAO clinical criteria in medical necessity reviews; update its audit protocols to address the issues identified in this report . . . ; and direct MAOs to take additional steps to identify and address vulnerabilities that can lead to manual review errors and system errors.”

Following these troubling OIG findings, on November 3, 2023, members of the United States House of Representatives noted their concerns to the Centers for Medicare and Medicaid Services (CMS) over the “increased reliance on artificial intelligence . . . or algorithmic software” by MA plans to guide coverage decisions. These Representatives expressed that the use of AI software, such as naviHealth, myNexus, and CareCentrix, “led to coverage decisions that are more restrictive than allowed under traditional Medicare rules, as well as more frequent and repeated denials of care.”

MA plans responded by saying AI was providing guidance to improve patient care, but those Representatives feared it was instead being utilized to make coverage determinations. Thus, they called on CMS to “increase oversight” of the AI tools being utilized by MA plans.

The American Medical Association’s AI Concerns

The American Medical Association (AMA) has also weighed in on the debate over the use of AI by insurers. At its June 2023 annual meeting, the AMA House of Delegates adopted a new policy “calling for greater regulatory oversight of insurers’ use of AI in reviewing patient claims and prior authorization requests.” The policy also “calls for health insurers utilizing AI technology to implement a thorough and fair process that is based on clinical criteria and includes reviews by physicians and other health care professionals with expertise for the service under review and no incentive to deny care.”

Following up on this policy, in November 2023, the AMA Board of Trustees issued seven principles for the development of equitable and responsible AI tools and use in healthcare.

These key principles “call for comprehensive policies that mitigate risks to patients and physicians, ensuring that the benefits of AI in health care are maximized while potential harms are minimized.” The AMA principles include the following categories:

1. Oversight – encouragement of a “whole of government” approach to mitigating the risks of AI in healthcare while also acknowledging the critical role non-government entities must play in this oversight
2. Transparency – emphasis on transparency and developing laws that mandate the sharing of key characteristics and information regarding the design, development, and deployment processes for AI in healthcare
3. Disclosure and Documentation - appropriate disclosure and documentation when AI directly impacts patient care, access to care, medical decision making, communications, or the medical record
4. Generative AI – development and adoption of policies to anticipate and minimize negative impacts that have been associated with generative AI
5. Privacy and Security – prioritization of robust measures to protect patient privacy and data security when developing AI tools
6. Bias Mitigation – proactive identification and mitigation of bias in AI algorithms to promote fair and inclusive care that is free from discrimination
7. Liability – advocacy for the limitation of physician liability when utilizing AI tools

Patient Suits Challenging the Use of AI

The OIG, Congress, and the AMA are not the only ones responding to AI’s expansion into healthcare and raising concerns over its misuse. Patients are also pushing back as evidenced by recent lawsuits against several insurers.

In July 2023, a lawsuit was filed against Cigna Health in the United States District Court for the Eastern District of California. That Complaint alleges that during two months in 2022, over 200,000 payment requests were denied utilizing AI tools, with an average estimated review time by a doctor of only 1.2 seconds per request. If proven, this case would validate the concerns that under the guise of a tool to assist employees and speed up approvals and the delivery of care/reimbursement, AI is being misused with the purpose of denying pre-authorizations and/or reimbursement to increase insurers’ bottom lines.

Similarly, a lawsuit was filed in November 2023 against UnitedHealthcare in the United States District Court for the District of Minnesota. According to that Complaint, “[t]he nH Predict AI Model determines Medicare Advantage

patients' coverage criteria in post-acute care settings with rigid and unrealistic predictions for recovery. Relying on the nH Predict AI Model, Humana purports to predict how much care an elderly patient 'should' require but overrides real doctors' determinations as to the amount of care a patient in fact requires to recover." Moreover, the lawsuit alleges Humana limits employees from deviating more than 1% from the number of days predicted by the AI Model thereby creating a financial windfall to Humana due to the increased number of denied claims.

Most recently, in December 2023, a lawsuit was filed against Humana, in the United States District Court for the Western District of Kentucky. That suit alleges that Humana is improperly utilizing an AI Model to "override real treating physicians' determinations as to medically necessary care patients require." To do so, it is claimed that Humana wrongfully bases its claim denials on aggregated patient data rather than the opinions of doctors reviewing the specific circumstances of individual patients.

While it is too early to tell how these suits will fare, it is expected that each insurer will aggressively defend their AI practices as consistent with all Medicare and MA requirements under the law. Yet, close attention should be paid to their outcomes as these suits will shed further light on AI vulnerabilities and possible misuse. They will also likely encourage action by policymakers and impact pending policy decisions.

Federal Government Action

In the midst of these various investigations, policy statements/positions, and lawsuits, the White House has begun to assert its position that there must be standards for the appropriate use of AI in healthcare.

On October 30, 2023, President Biden released an Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. Included were a series of directives to the Secretary of Health and Human Services (HHS) "[t]o help ensure the safe, responsible deployment and use of AI in the healthcare, public-health, and human-services sectors." While short on specifics, it sent a clear message to HHS of the importance of developing guidance for protecting privacy in the use of AI in healthcare.

In response, the first concrete action came in the form of a February 6, 2024 CMS policy statement formatted as a set of frequently asked questions that included whether the "new rules on clinical coverage criteria for basic Medicare benefits mean that MA organizations cannot use algorithms or artificial intelligence to make coverage decisions."

CMS' response may be a sign of government skepticism over the unchecked utilization of AI and its propensity

toward misuse by insurers to deny Government financed medical benefits. CMS made clear that while "[a]n algorithm or software tool can be used to assist MA plans in making coverage determinations . . . it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made."

For example, CMS clarified that an algorithm or software tool "that determines coverage based on a larger data set instead of the individual patient's medical history, the physician's recommendations, or clinical notes" would not comply with MA regulations and thus not be proper. CMS underscored that this standard applies to assessing coverage for items such as inpatient admissions and basic benefits. CMS further emphasized that "[b]ecause publicly posted coverage criteria are static and unchanging, artificial intelligence cannot be used to shift the coverage criteria over time." These AI tools also "cannot apply other internal coverage criteria that have not been explicitly made public and adopted in compliance with the evidentiary standard" under the MA regulations.

CMS concluded its comments by emphasizing its concern over the algorithms underpinning AI "exacerbate[ing] discrimination and bias." Given that the Affordable Care Act expressly prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities, "MA organizations should, prior to implementing an algorithm or software tool, ensure that the tool is not perpetuating or exacerbating existing bias, or introducing new biases." Thus, insurance companies must be cognizant of how their AI tool is trained as the Government will be sensitive to any suggestion of bias in these systems in its oversight.

Conclusion

While many questions remain regarding what direction AI will take in the future, this new technology is only going to further integrate itself into the fabric of the healthcare sector. In response, insurers are almost certain to continue deploying this technology in the claims adjudication, payment, and appeal processes.

For those insurers and those responsible for their oversight, the focus must be on ensuring AI technology is being utilized appropriately to advance care rather than as a tool to withhold patient medical benefits and provider reimbursement. This is only the first chapter in the AI story. There are many more yet to be written.

About the Authors:

Robert B. Hille is a Partner in the firm's Litigation and Healthcare Departments, with white-collar experience encompassing both state and federal investigations, including those related to healthcare fraud and abuse and federal False Claims Act cases. Bob is also a former President of the New Jersey State Bar Association and served as the Co-Chair of the Ethics and Regulatory Work Group on the New Jersey State Bar Association Task Force on Artificial Intelligence (AI) in the Law. He can be reached by email at rhille@greenbaumlaw.com.

John W. Kaveney, Esq. is a Partner in the Healthcare and Litigation Departments at Greenbaum, Rowe, Smith & Davis LLP, where he concentrates his legal practice on corporate compliance matters, information privacy and data security, and Medicare reimbursement matters, as well as general regulatory guidance and healthcare litigation. He can be reached by email at jkaveney@greenbaumlaw.com.

¹ 15 U.S.C. §9401(3).

² *Id.*

³ <https://oig.hhs.gov/oei/reports/oei-09-16-00410.pdf>

⁴ *Id.*

⁵ *Id.*

⁶ <https://oig.hhs.gov/oei/reports/OEI-09-18-00260.asp?hero=mao-report-04-28-2022>

⁷ *Id.*

⁸ *Id.*

⁹ *Id.*

¹⁰ <https://chu.house.gov/sites/evo-subsites/chu.house.gov/files/evo-media-document/chu-nadler-ma-ai-oversightletter-11.3.2023.pdf>

¹¹ *Id.*

¹² *Id.*

¹³ <https://www.ama-assn.org/press-center/press-releases/ama-adopts-policy-calling-more-oversight-ai-priorauthorization>

¹⁴ *Id.*

¹⁵ <https://www.ama-assn.org/system/files/ama-ai-principles.pdf>

¹⁶ <https://www.ama-assn.org/press-center/press-releases/ama-issues-new-principles-ai-development-deployment-use>

¹⁷ *Id.*

¹⁸ <https://s3.documentcloud.org/documents/23885679/cigna-complaint.pdf>

¹⁹ *Id.*

²⁰ <https://cdn.arstechnica.net/wp-content/uploads/2023/11/class-action-v-unitedhealth-and-navihealth-1.pdf>

²¹ *Id.*

²² *Id.*

²³ <https://storage.courtlistener.com/recap/gov.uscourts.kywd.128636/gov.uscourts.kywd.128636.736.0.pdf>

²⁴ *Id.*

²⁵ <https://www.whitehouse.gov/briefing-room/presidential-actions/2023/10/30/executive-order-on-the-safe-secure-and-trustworthy-development-and-use-of-artificial-intelligence/>

²⁶ <https://cdn.arstechnica.net/wp-content/uploads/2024/02/cms-memo-2624-faqs-related-to-coverage-criteria-andutilization-management-requirements-in-cms-final-rule-cms-4201-f.pdf>

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ *Id.*

Mark Your Calendar

New Jersey HFMA Regulatory and Reimbursement Committee Fall 2024 Event

September 5, 2024, 10am - 1pm

Webinar

Night Out at the Ballgame!

September 10, 2024, 5:30pm

Patriot's Stadium, Bridgewater, NJ

Annual Institute

October 9-11, 2024

Hard Rock Hotel & Casino, Atlantic City, NJ

Watch for updates on all of these events, or visit the Chapter website at hfmanj.org