

Date of Hearing: July 2, 2024

ASSEMBLY COMMITTEE ON PRIVACY AND CONSUMER PROTECTION

Rebecca Bauer-Kahan, Chair

SB 1120 (Becker) – As Amended June 20, 2024

AS PROPOSED FOR CONSENT

AS PROPOSED TO BE AMENDED

SENATE VOTE: 37-0

SUBJECT: Health care coverage: utilization review

SYNOPSIS

Artificial intelligence (AI) models can process enormous datasets, identify hidden patterns, and make decisions with a degree of accuracy and reliability that vastly exceeds human capabilities. But the datasets AI are trained on are often contaminated with bias, and the inferences AI draw from intricate patterns in these datasets are often inscrutable. Rather than eliminating human bias, AI can reinforce and mask it with the guise of mathematical neutrality. Without human-centered oversight, particularly in consequential contexts such as healthcare, the impacts can be catastrophic.

The bill, sponsored by California Medical Association, seeks to ensure that physicians exercise oversight over utilization review decisions in order to foster the best health outcomes for patients. The bill would require health plans and insurers to comply with specific requirements when using AI and other similar decision-making tools for utilization management review or utilization management functions. Additionally, the bill would require that denials, delays, or modifications of health care services must be made by a licensed physician or other health care provider competent to evaluate the specific clinical issues involved in the health care services requested. The bill is supported by a number of health organizations as well as by Oakland Privacy.

The bill is opposed by California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans unless it is amended to omit the provision requiring that a licensed physician or health care provider has final approval of any utilization review decisions involving an AI. The bill passed the Assembly Health Committee on a 16-0 vote.

As set forth below, proposed amendments make various clarifying changes to the bill.

SUMMARY: Requires that health care service plans and disability insurers ensure that the use of AI and other similar tools for the purpose of utilization review or utilization management functions take certain steps to ensure that the AI is deployed with proper oversight. Requires health plans and insurers to ensure that a licensed physician supervises any AI-based decisions that approve, modify, or deny a patient's care. Specifically, **this bill:**

- 1) Requires that health care service plans and disability insurers ensure that the use of AI or other similar tools for the purpose of utilization review or utilization management functions ensure all of the following:
 - The tool bases its determination on information specific to the patient.
 - The tool does not supplant health care provider decisionmaking.
 - The use of the tool does not adversely discriminate against individuals on the basis of protected characteristics.
 - The tool is fairly and equitably applied.
 - The tool is open to inspection.
 - Disclosures pertaining to the use and oversight of the tool are contained in the written policies and procedures.
 - The tool's performance, use, and outcomes are periodically reviewed.
 - The tool is periodically reviewed and revised in order to maximize accuracy and reliability.
 - Patient data is not used beyond its intended and stated purpose, consistent with medical privacy laws.
- 2) Requires that a denial, delay, or modification of health care services based on medical necessity be made by a licensed physician or other health care provider competent to evaluate the specific clinical issues involved in the health care services requested by the provider, as specified.

EXISTING LAW:

- 1) Establishes the Knox-Keene Health Care Service Plan Act of 1975, provides for the licensure and regulation of health care service plans by the Department of Managed Health Care. (Health & Saf. Code § 1340, *et seq.*)
- 2) Provides for the regulation of disability insurers by the Department of Insurance. (Ins. Code § 106, *et seq.*)
- 3) Authorizes a health care service plan or disability insurer to use prior authorization and other utilization review or utilization management functions, under which a licensed physician or a licensed health care professional who is competent to evaluate specific clinical issues may approve, modify, delay, or deny requests for health care services based on medical necessity. (Health & Saf. Code § 1367.01(e); Ins. Code § 10123.135(e).)
- 4) Requires a health care service plan or disability insurer, including those plans or insurers that delegate utilization review or utilization management functions to medical groups, independent practice associations, or to other contracting providers, to comply with specified

requirements and limitations on their utilization review or utilization management functions. (Health & Saf. Code § 1367.01; Ins. Code § 10123.135.)

- 5) Authorizes the Director of the Department of Managed Health Care or the Insurance Commissioner to assess an administrative penalty to a health care service plan or disability insurer, as applicable, for failure to comply with the above-described requirements. (Health & Saf. Code § 1374.9; Ins. Code § 12968.)

FISCAL EFFECT: As currently in print, this bill is keyed fiscal.

COMMENTS:

1) **Background.** AI uses algorithms – sets of rules – to transform inputs into outputs. Inputs and outputs can be anything a computer can process: numbers, text, audio, video, or movement. This is because AI is not fundamentally different from other computer functions. Its novelty lies in its application: unlike standard computer functions, AI is able to accomplish tasks that are normally performed by humans.

Computers can generally draw upon vast quantities of digitally-encoded data, processing it faster than any human being. A recent *New York Times* article described the development of a breast cancer screening system that uses AI:

From the millions of cases the system is fed, the technology creates a mathematical representation of normal mammograms and those with cancers. With the ability to look at each image in a more granular way than the human eye, it then compares that baseline to find abnormalities in each mammogram.

Last year, after a test on more than 275,000 breast cancer cases, Kheiron [Medical Technologies, the system’s developer] reported that its A.I. software matched the performance of human radiologists when acting as the second reader of mammography scans. It also cut down on radiologists’ workloads by at least 30 percent because it reduced the number of X-rays they needed to read. In other results from a Hungarian clinic last year, the technology increased the cancer detection rate by 13 percent because more malignancies were identified.¹

But care should be taken to avoid what New York University Professor Meredith Broussard describes as “the notion that computers are more ‘objective’ or ‘unbiased’ because they distill questions and answers down to mathematical evaluation...an unwavering faith that if the world used more computers, and used them properly, social problems would disappear and we’d create a digitally enabled utopia.”² Many aspects of the real world are not reducible to data, and many complex situations present competing demands that human beings remain best equipped to assess. Illustrations of such pitfalls follow.

Problematic correlations. In one example, a hospital trained AI models on a dataset of 15,000 pneumonia patients in order to develop a model that could identify which pneumonia patients were at the greatest risk in order to triage new patients. During testing, it was discovered that one

¹ Santariano & Metz, “Using A.I. to Detect Breast Cancer That Doctors Miss,” *New York Times*, Mar. 5, 2023, <https://www.nytimes.com/2023/03/05/technology/artificial-intelligence-breast-cancer-detection.html>.

² Broussard, “Artificial Unintelligence,” *MIT Press*, 2019.

of the most accurate models recommended outpatient status for asthmatics—a life-threateningly dangerous error based on a statistical correlation: asthmatics are less likely to die from pneumonia than the general population precisely because asthma is such a serious risk factor that asthmatics automatically get elevated care.³

Bias and discrimination. Bias and discrimination can result from skewed training data. There is a famous saying in computer science: “garbage in, garbage out.” The performance of an AI is directly impacted by the quality, quantity, and relevance of the data used to train it.⁴ If the data used to train the AI is biased, the tool’s outputs will be similarly biased. When AIs are deployed in healthcare, biased historical data can lead to patients being recommended substandard care on the basis of their race or ethnicity.

In 2007, an AI was developed to help doctors estimate whether it was safe for people who had delivered previous children through cesarean section to deliver subsequent children vaginally – a risky procedure. The AI considered various health relevant factors as it made its decision, such as the woman’s age, her reason for the previous cesarean, and how long ago the cesarean had been performed. However, a 2017 study found that the AI was biased; it predicted Black and Latino people were less likely to have a successful vaginal birth after a cesarean than non-Hispanic white women. As a result, doctors performed more cesareans on Black and Latino people than on white people.⁵ These discrepancies perpetuate historical biases – Black Americans, for example, have historically received a lower standard of healthcare than their white counterparts.⁶

Issues with interpretability. Issues such as those described above can be masked by the inscrutability of the most advanced AI models. AI that use “deep learning”—machine learning that uses multilayer (deep) neural networks to analyze vast datasets—can infer intricate patterns and relationships from complicated data, but exactly how they do so is not always obvious. Deep neural networks are sometimes criticized for being “black boxes” that generate predictions and outcomes that cannot be clearly explained.⁷ “It’s often observed in the field that the most powerful models are on the whole the least intelligible, and the most intelligible are among the least accurate.”⁸ If a decision-making process cannot be explained and clearly understood, how can it be guaranteed that the decision reached is fair and free of bias? AI experts are currently researching ways to solve this problem.

Algorithmic denials of care. Last year, a class action lawsuit alleged that UnitedHealth Group unlawfully used an algorithm to deny rehabilitative care to sick Medicare Advantage patients. According to *Forbes*:

³ Brian Christian, “The Alignment Problem: Machine Learning and Human Values” (Norton 2020, First Ed.), pp. 82-84.

⁴ Rohit Sehgal, “AI Needs Data More Than Data Needs AI”, *Forbes*, Oct. 5, 2023, <https://www.forbes.com/sites/forbestechcouncil/2023/10/05/ai-needs-data-more-than-data-needs-ai/>.

⁵ Caleb J Colón-Rodríguez, “Shedding Light on Healthcare Algorithmic and Artificial Intelligence Bias,” *U.S. Department of Health & Human Services Office of Minority Health*, Jul. 12, 2023, minorityhealth.hhs.gov/news/shedding-light-healthcare-algorithmic-and-artificial-intelligence-bias.

⁶ California Task Force to Study and Develop Reparation Proposals for African American, “Final Report,” California.

⁷ Neil Savage, “Breaking into the black box of artificial intelligence,” *Nature*, March 29, 2022.

⁸ Brian Christian, “The Alignment Problem: Machine Learning and Human Values” (Norton 2020, First Ed.), p. 85.

The lawsuit, filed in the US District Court for the District of Minnesota, accuses UnitedHealthcare of utilizing the nH Predict algorithm to make health-care determinations, leading to the premature and bad-faith discontinuation of payment for healthcare services. The plaintiffs, representing the estates of deceased individuals covered by Medicare Advantage plans provided by UnitedHealthcare, claim that they were forced to pay out of pocket for medically necessary care due to claim denials by the insurer. This suit potentially involve thousands of individuals and billions of dollars of damages, according to a lawyer for the plaintiffs.⁹

A letter penned last week by Senator Elizabeth Warren and a bipartisan group of Congress members urged the Centers for Medicare & Medicaid Services to take a more proactive role in monitoring plans' use of AI. "Given that we do not know what inputs are used for the algorithms and AI tools currently being used, it is difficult to know the accuracy of the information they generate and whether the inputs comply with the regulations."¹⁰ The letter called for a prohibition on the use of AI tools and software from use in coverage denials until a systematic review of their use can be completed. "These tools apply a generalized need for care to an individual beneficiary's situation, resulting in generalizations instead of person-centered approaches to care, which is antithetical to the mission of the Medicare program."¹¹

2) **Prior Authorization (PA).** According to the Assembly Health Committee's analysis:

PA is a decision by a health plan or insurer that a health care service, treatment plan, prescription drug, or durable medical equipment is medically necessary. The health plan or insurer may require preauthorization for certain services before an individual receives them, except in an emergency.

Health plans and insurers are subject to various requirements in California, including an obligation to file policies and procedures that describe UR or UM functions, used to authorize, modify, or deny health care services under the benefits provided by the health plan. Additionally, California law requires these policies and procedures to ensure that decisions based on the medical necessity of proposed health care services are consistent with criteria or guidelines that are supported by clinical principles and processes. Finally, current law prohibits an individual, other than a licensed physician or licensed health care professional who is competent to evaluate the specific clinical issues involved in the health care services requested by the provider, from denying authorization for health care services based on medical necessity.

According to the Kaiser Family Foundation, insurers use PA to reduce payments for care that is not medically necessary or appropriate, which in turn helps to keep premiums down. However, PA has come under scrutiny for creating unnecessary burdens for providers, plans, and patients. Patients can find it challenging to know what services require PA, the process and criteria plans use to make a PA coverage decision, and whether providers are giving the needed information to a plan to determine coverage. Inefficient processes can delay decisions

⁹ Douglas B. Laney, "AI Ethics Essentials: Lawsuit Over AI Denial of Healthcare" (Nov. 16, 2023) *Forbes*, <https://www.forbes.com/sites/douglaslaney/2023/11/16/ai-ethics-essentials-lawsuit-over-ai-denial-of-healthcare/>.

¹⁰ Letter to the Honorable Chiquite Brooks-LaSure (June 25, 2024), p. 2, <https://www.documentcloud.org/documents/24777080-final-chu-nadler-warren-letter-to-cms-to-increase-oversight-of-ai-in-medicare-advantage-coverage-decisions-06252024>.

¹¹ *Ibid.*

and consequently access to care, increasing health risks to patients. Improper denials may increase patient out-of-pocket costs or cause patients to abandon care. The process itself may have a chilling effect on individuals seeking out care and providers recommending it.

In December 2023, the National Association of Insurance Commissioners issued guidance that the use of AI should be designed to mitigate the risk that the insurer's use of AI will result in adverse outcomes for consumers. Insurers should have robust governance, risk management controls, and internal audit functions, which all play a role in mitigating such risk including, but not limited to, unfair discrimination in outcomes resulting from predictive models and AI systems. The guidance reminds insurance carriers that decisions impacting consumers that are made or supported by advanced analytical and computational technologies, including AI, must comply with all applicable insurance laws and regulations, including unfair trade practices.

3) **Author's statement.** According to the author:

Recent reports of automated decision tools inaccurately denying provider requests to deliver care is worrisome. While artificial intelligence (AI) has the potential to improve healthcare delivery, trained medical professionals who understand the complexities of each patient's situation need to have the final say. Wrongful denial of insurance claims based on AI algorithms can lead to serious health consequences, and even death. This bill strikes a common sense balance that puts safeguards in place for automated decision tools without discouraging companies from using this new technology.

4) **This bill.** Existing law authorizes a health care service plan or disability insurer to use prior authorization and other utilization review or utilization management functions, under which a licensed physician or a licensed health care professional who is competent to evaluate specific clinical issues may approve, modify, delay, or deny requests for health care services based on medical necessity.

This bill, with regard to the use of AI and similar tools for the purpose of utilization review or utilization management functions, requires that health care service plans and disability insurers ensure all of the following:

- The tool bases its determination on information specific to the patient.
- The tool does not supplant health care provider decisionmaking.
- The use of the tool does not adversely discriminate against individuals on the basis of protected characteristics.
- The tool is fairly and equitably applied.
- The tool is open to inspection.
- Disclosures pertaining to the use and oversight of the tool are contained in the written policies and procedures.
- The tool's performance, use, and outcomes are periodically reviewed.

- The tool is periodically reviewed and revised in order to maximize accuracy and reliability.
- Patient data is not used beyond its intended and stated purpose, consistent with medical privacy laws.

The bill also requires that a denial, delay, or modification of health care services based on medical necessity be made by a licensed physician or other health care provider competent to evaluate the specific clinical issues involved in the health care services requested by the provider, as specified. In doing so the bill helps to ensure that AI used to decide the level of care a person receives, if any, is subject to appropriate human oversight and thus is deployed in a responsible manner. As aptly stated by Oakland Privacy:

There are a number of reasons why health care automated decision-making systems should have physician supervision of denials. [AI systems] are fed sets of criteria to govern their decision-making processes, and these criteria can be impacted by human errors, including inaccurate data entry and flawed weights for one or more factors. Additionally, medical research and findings can change over time, including recommended treatment protocols, and there can be time gaps between cutting-edge medical research and the reformulation of medical decision-making algorithms. We also know that some forms of bias exist in the medical system, and those biases likely carry over into the data and formula fed to the automatic system. Fighting bias is an ongoing effort, but institutionalizing it permanently in machine learning is an impediment to that struggle. Finally, some medical care decisions may require judgment that goes beyond mathematical patterns.

5) **Committee amendments.** The author has agreed to a number of clarifying changes that recast the provision. The amendments are as follows:

Amendment #1: Make the following changes to section 1367.01 of the Health and Safety Code:

~~(k) (1) Use of algorithms or artificial intelligence by or on behalf of a health care service plan or a specialized health care service plan covering dental services~~ ***A health care service plan or specialized health care service plan that uses an artificial intelligence, algorithm, or other software tool for the purpose of utilization review or utilization management functions, or that contracts with or otherwise works through an entity that uses an artificial intelligence, algorithm, or other software tool, for the purpose of utilization review or utilization management functions, shall comply with this section*** ~~(2) Algorithms, artificial intelligence, and other software tools used by or on behalf of a health care service plan or a specialized health care service plan covering dental services for the purpose of utilization review or utilization management functions for health care services shall comply with~~ ***and shall ensure*** all of the following:

~~(A) Be based upon~~ ***The tool bases its determination on the following information, as applicable:***

~~(i) An enrollee's medical or dental history, as applicable, and~~

~~(ii) Individual clinical circumstances as presented by the requesting provider, as well as~~

~~(iii) Other relevant clinical information contained in the enrollee's medical or dental record, and not supplant health care provider decisionmaking.~~

~~(B) The tool does not supplant health care provider decisionmaking.~~

~~(B) Not directly or indirectly discriminate~~ **(C) The use of the tool does not adversely discriminate, directly or indirectly,** against an individual on the basis of race, color, religion, national origin, ancestry, age, sex, gender, gender identity, gender expression, sexual orientation, present or predicted disability, expected length of life, degree of medical dependency, quality of life, or other health conditions.

~~(C) Be~~ **(D) The tool is** fairly and equitably applied.

(E) The tool is open to inspection.

~~(D) Be open to inspection and disclosed~~ **(F) Disclosures pertaining to the use and oversight of the tool are contained** in the written policies and procedures, *as* required by subdivision (b).

~~(E) Be governed by policies that establish accountability for~~ **(G) The tool's** performance, use, and outcomes ~~that are~~ *periodically* reviewed and revised ~~for~~ *in order to maximize* accuracy and reliability.

~~(F) Not allow data to be~~ **(H) Patient data is not** used beyond its intended and stated purpose, *consistent with the Confidentiality of Medical Information Act (Part 2.6 (commencing with Section 56) of Division 1 of the Civil Code and the federal Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191).*

~~(G) Not~~ **(I) The tool does not** directly or indirectly cause harm to the enrollee.

~~(2) Notwithstanding paragraphs (1) and (2),~~ a denial, delay, or modification of health care services based on medical necessity shall be made by a licensed physician or other health care provider competent to evaluate the specific clinical issues involved in the health care services requested by the provider, as provided in subdivision (e), by considering the requesting provider's recommendation, ~~and based on~~ the enrollee's medical or dental history, as applicable, and individual clinical circumstances.

(3) For purposes of this subdivision, "artificial intelligence" means an engineered or machine-based system that varies in its level of autonomy and that can, for explicit or implicit objectives, infer from the input it receives how to generate outputs that can influence physical or virtual environments.

Amendment #2: Make equivalent changes in Section 10123.135 of the Insurance Code.

6) Related legislation. AB 2930 (Bauer-Kahan) establishes a statutory framework to further the safe and informed use of automated decision tools across various sectors of the economy. The bill is pending in the Senate Judiciary Committee.

AB 3030 (Calderon) requires a health facility, clinic, physician's office, or office of a group practice that uses generative artificial intelligence to generate written or verbal patient communications pertaining to patient clinical information to ensure that those communications

include a disclaimer that indicates to the patient that the communication was generated by generative artificial intelligence and clear instructions on how the patient may contact a human person. The bill is pending in the Senate.

ARGUMENTS IN SUPPORT: The bill's sponsor, the California Medical Association, writes:

This bill would require that a licensed physician or health care provider has final approval of any utilization review decisions that are made or assisted by AI decision making tools or algorithms used by a health care insurer. While AI tools can improve access to care and assist providers, they have also faced criticism for inaccuracies and biases. This bill addresses those issues by guaranteeing that a provider has final approval of utilization review decisions when AI is being used.

Additionally, this bill includes safeguards to ensure AI, or algorithms used in utilization review do not discriminate against individuals based on their identity. As powerful as many AI tools are, they can be compromised when they rely on faulty, outdated, or biased data sources, leading to improper treatment recommendations. SB 1120 adopts federal guidance requiring health plans to make certain that their AI technology is free from such problems. Without the Physicians Make Decisions Act, patients could have essential medical services denied by AI when being used for utilization review by health insurers.

AI has been and will continue to be an essential tool in improving health care access and affordability for patients, but physicians must have oversight of critical utilization review decisions to allow for the best health outcomes for our communities. This bill provides essential guardrails to allow us to continue successfully integrating AI into our health care system.

ARGUMENTS IN OPPOSITION: Adopting an oppose-unless-amended position, the California Association of Health Plans, the Association of California Life and Health Insurance Companies, and America's Health Insurance Plans jointly write:

Health plans and insurers have been using automated decision tools for years, as these tools are critical to increasing efficiencies, informing decision-making, and reducing administrative burdens. Current practice dictates that these tools are not used in isolation to make utilization management decisions and that these tools are monitored by appropriate health professionals. While we appreciate that much of the bill seems to mirror current federal guidelines regarding the use of AI tools, we are concerned that the bill includes narrow clinical peer review language that goes well beyond existing law. SB 1120 would substantially limit who is allowed to conduct utilization reviews by requiring the reviewing provider be within the same or similar specialty as the requesting provider. Current law already requires that all peer review must be done by a competent health professional within a timely manner. If the treating provider disagrees with the reviewing provider, current law already affords a process for the resolution of the dispute through independent medical review. We believe this provision is unnecessary and will only add more costs to the health care system. We respectfully request that the language outlined in Health and Safety Code 1367.07(k)(3) be removed from the bill.

REGISTERED SUPPORT / OPPOSITION:

Support

California Medical Association (CMA) (sponsor)
California Chapter American College of Cardiology
California Dental Association
California Hospital Association
California Life Sciences
California Podiatric Medical Association
California Rheumatology Alliance
CPCA Advocates, Subsidiary of The California Primary Care Association
Oakland Privacy
San Francisco Marin Medical Society

Opposition

None on file.

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