

SB0987_FAV_MedChi_AI - Health Software & Health In

Uploaded by: Danna Kauffman

Position: FAV



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Senate Finance Committee
February 27, 2025

Senate Bill 987 – *Artificial Intelligence – Health Software and Health Insurance Decision Making*
POSITION: SUPPORT

The Maryland State Medical Society (MedChi), the largest physician organization in Maryland, supports Senate Bill 987.

This bill would require the Maryland Health Care Commission (MHCC) to maintain a registry of artificial intelligence health software that may be distributed or operated in Maryland. The bill also states that health insurance carriers, as defined in the bill, may not use artificial intelligence (AI) to decide or directly influence a health care decision or a decision directly related to health care.

MedChi supports efforts to regulate AI-controlled processes in patient care and to ensure transparency. The MHCC registry required under the bill, as well as the restriction on the use of AI in health care decisions, help to accomplish that goal in Maryland. We believe that while AI can be used to enhance patient care, streamline processes, and improve diagnostic accuracy, there must be clear regulatory oversight to ensure that AI is not used to replace the expertise of trained medical professionals. Additionally, the registry will provide critical oversight by tracking the deployment of AI used in healthcare in Maryland. This requirement will bring necessary transparency to physicians, patients, and regulators to better understand which AI tools are in use and how they may be influencing medical decisions.

We respectfully request a favorable report of Senate Bill 987.

For more information call:

Danna L. Kauffman
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Christine K. Krone
410-244-7000

SB 987 - MIA - LOS.pdf

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Position: FAV

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Date: February 27, 2025

Bill # / Title: Senate Bill 987 - Artificial Intelligence - Health Software and Health Insurance Decision Making

Committee: Senate Finance Committee

Position: Support

The Maryland Insurance Administration (MIA) appreciates the opportunity to share its support for Senate Bill 987.

Senate Bill 987 requires the Maryland Health Care Commission (MHCC) to maintain a registry of artificial intelligence (AI) health software that may be distributed or operated in the State and prohibits a person from distributing or operating AI health software unless the software is registered with MHCC. Additionally, Senate Bill 987 prohibits health insurance carriers from using AI to decide or directly influence a health care decision or a decision directly related to health care; however, it clarifies that the legislative intent is not to prevent carriers from using AI for tasks or decisions unrelated to health care.

As outlined in a recent Bulletin¹ published by the MIA regarding the use of AI systems in insurance, “AI techniques are deployed across all stages of the insurance life cycle, including product development, marketing, sales and distribution, underwriting and pricing, policy servicing, claim management, and fraud detection.” AI is transforming the insurance industry, but it also presents unique risks to consumers, including potential inaccuracies, data vulnerabilities, and a lack of transparency in how these tools are being used.

As AI continues to be rapidly developed and relied upon by carriers, it is essential to establish a strong foundation of transparency and information collection for regulatory agencies. Furthermore, the National Association of Insurance Commissioners’ (NAIC) consumer representatives recently shared a report on Artificial Intelligence and Health Insurance, specifically regarding the use of AI in utilization management, making recommendations for

¹<https://insurance.maryland.gov/Insurer/Documents/bulletins/24-11-The-Use-of-Artificial-Intelligence-Systems-in-Insurance.pdf>

policymakers on enforcement.² The MIA believes that Senate Bill 987's registry is an important step in moving forward the recommendations made in this report in Maryland.

The legislation also prohibits the use of AI in deciding or directly influencing a health care decision or a decision related to health care. It is the MIA's view that current Maryland law prohibits health insurers from making determinations of medical necessity via AI. Importantly, this legislation also prohibits direct influencing of a health care decision by AI - a strong consumer protection.

For these reasons, the MIA urges a favorable committee report for Senate Bill 987.

² Report available at https://content.naic.org/sites/default/files/national_meeting/Final-CR-Report-AI-and-Health-Insurance-11.14.24.pdf

SB987_MDPpsychologicalAssoc_FAV

Uploaded by: Taylor Dickerson

Position: FAV



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February 25, 2025

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Senator Antonio Hayes, Vice Chair
Finance Committee
Miller Senate Office Building, 3 East
Annapolis, MD 21401

RE: SB 987 Artificial Intelligence – Health Software and Health Insurance Decision Making

Position: SUPPORT

Dear Chair, Vice-Chair and Members of the Committee:

The Maryland Psychological Association, (MPA), which represents over 1,000 doctoral level psychologists throughout the state, asks the Senate Finance Committee to **FAVORABLY report on SB 987**.

SB 987 would require the Maryland Health Care Commission to establish and maintain a registry of approved artificial intelligence (AI) software authorized for use in the state's healthcare system. The bill mandates that the Commission adopt regulations to define AI software and determine the specific information that must be collected for inclusion in the registry. This initiative aims to enhance oversight, ensure transparency, and promote the safe and effective use of AI technology in healthcare settings across Maryland. In addition, the bill benefits the health insurance industry by providing standardized, vetted AI tools that can improve efficiency in claims processing, fraud detection, and risk assessment. By ensuring that only approved AI software is used, insurers can reduce errors, enhance patient outcomes, and build greater trust with healthcare providers and policyholders.

We urge the Committee to issue a **favorable report on SB 987**. If we can be of any further assistance, please do not hesitate to contact MPA's Legislative Chair, Dr. Stephanie Wolf, JD, Ph.D. at mpalegislativcommittee@gmail.com.

Respectfully submitted,

David Goode-Cross, Ph.D.

David Goode-Cross, Ph.D.

President

Stephanie Wolf, JD, Ph.D.

Stephanie Wolf, JD, Ph.D.

Chair, MPA Legislative Committee

cc: Richard Bloch, Esq., Counsel for Maryland Psychological Association
Barbara Brocato & Dan Shattuck, MPA Government Affairs

DOCS-#239050-v1-SB_987_League_FWA_-_AI.pdf

Uploaded by: Philemon Kendzierski

Position: FWA



15 School Street, Suite 200
Annapolis, Maryland 21401
410-269-1554

February 27, 2025

The Honorable Pam Beidle
Chair, Senate Finance Committee
3 East
Miller Senate Office Building
Annapolis, MD 21401

Senate Bill 987 – Artificial Intelligence - Health Software and Health Insurance Decision Making

Dear Chair Beidle,

The League of Life and Health Insurers of Maryland, Inc. respectfully requests a favorable with amendments report on *Senate Bill 987– Artificial Intelligence - Health Software and Health Insurance Decision Making*. We appreciate the sponsor bringing this important piece of legislation to codify responsible use of technology.

Artificial intelligence (AI) is a transformational tool that is reshaping industries across the country and the world. In insurance, AI is a tool that can be deployed to improve the customer experience by simplifying processes in an efficient and accurate manner. Carriers use AI to speed up claims payments, flag electronic medical record overlap for care coordination, and create efficiencies across the continuum that reduces the administrative costs of health care.

League members are committed to harnessing the potential of AI, while also minimizing risks and protecting consumers. This includes complying with all federal and state laws and regulations governing the use of AI, including Maryland Insurance Administration [Bulletin No. 24-11 - The Use of Artificial Intelligence Systems in Insurance](#). This bulletin, which was developed as a national model by the National Association of Insurance Commissioners directs carriers to develop, implement, and maintain a written program for the responsible use of AI systems. Additionally, it is important to note that no carrier uses artificial intelligence to administer adverse decisions for utilization review. Just to reiterate in a time of great misinformation, *zero* carriers deny care with AI – it is always a human that makes adverse decisions.

For the above reasons, we respectfully request that Senate Bill 987 be amended to mirror House Bill 820 (which has already passed the House Health & Government Operations Insurance & Pharmaceuticals Subcommittee), which codifies required actions related to the use of AI in utilization review. For these reasons, the League urges the committee to give Senate Bill 987 a favorable with amendments report.

Very truly yours,

A handwritten signature in black ink, appearing to read "Matthew Celentano", with a long horizontal stroke extending to the right.

Matthew Celentano
Executive Director

cc: Members, Senate Finance Committee

v2_[MD] SB 987_hcAI_TechNet.pdf

Uploaded by: margaret durkin

Position: UNF



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February 25, 2025

The Honorable Pam Beidle
Chair
Senate Finance Committee
Maryland Senate
3 East Miller Senate Office Building
11 Bladen Street, Annapolis, MD 21401

*RE: SB 987 (Lam) - Artificial Intelligence - Health Software and Health Insurance
Decision Making – Unfavorable*

Dear Chair Beidle and Members of the Committee,

On behalf of TechNet, I'm writing to share our comments on SB 987.

TechNet is the national, bipartisan network of technology CEOs and senior executives that promotes the growth of the innovation economy by advocating a targeted policy agenda at the federal and 50-state level. TechNet's diverse membership includes dynamic American businesses ranging from startups to the most iconic companies on the planet and represents over 4.5 million employees and countless customers in the fields of information technology, artificial intelligence, e-commerce, the sharing and gig economies, advanced energy, transportation, cybersecurity, venture capital, and finance. TechNet has offices in Austin, Boston, Chicago, Denver, Harrisburg, Olympia, Sacramento, Silicon Valley, Tallahassee, and Washington, D.C.

Artificial intelligence (AI), machine learning (ML), and the algorithms that often support artificial intelligence have generated policymaker interest. We acknowledge that as technological advances emerge, policymakers' understanding of how these technologies work is vital for responsible policymaking. Our member companies are committed to responsible AI development and use. TechNet works to ensure that the proper balance is struck between consumer protection and business innovation. As such, we're concerned about SB 987 as currently drafted.

We recognize and respect that the Maryland Health Care Commission (MHCC) has a role to play with respect to technology in care delivery. However, we are concerned about the bill's broad mandate that all AI health software, to be distributed or operated in the state, must register with the MHCC, or else face steep fines of up to \$10,000 per day.

SB 987 fails to define “artificial intelligence health software” and instead gives discretion to the MHCC to determine what software would need to be registered. Business success depends on certainty and our members are concerned that the lack of definition to comment on now will lead to uncertainty down the road as the MHCC potentially addresses how to define this software. Further, we believe that SB 987 gives wide latitude to the MHCC about what information should be collected for the registry, while at the same time lacking specifics on what might need to be included in this proposed registry, such as impact assessments, documentation, or testing. We are also concerned about the lack of protection for trade secrets, information that could create a security risk, or other confidential or proprietary information protected under state or federal law.

Additionally, the bill’s requirements could apply not only to AI applications in clinical care, but also healthcare AI applications used for things such as patient scheduling, patient billing, notetaking, patient appointment reminders, or other routine operational tasks. Practically speaking, this means that a single healthcare entity or individual provider could be required to register multiple AI applications annually.

Of note, the bill provides no exceptions for existing review and registration frameworks for AI in healthcare, such as those from the FDA, that qualify the use of technology in a clinical setting. Moreover, the bill provides no exception for important fraud detection use cases in clinical healthcare settings. Given the broad term “artificial intelligence health software”, a clear carveout for AI systems designed to mitigate fraud, found in other prominent AI regulations like the EU AI Act, is warranted.

We also note that the bill places restrictions on the use of AI by insurers. We are concerned that the scope of the prohibition is overly broad and harmful to consumers. As a preliminary matter, carriers do not make health care decisions. They make coverage decisions. Some of those decisions are contractually based in whether a health care service is covered or not. In other cases, coverage depends on an assessment of medical necessity or a similar analysis which under existing Maryland law requires that the analysis and decision be made by the appropriate medical professional. As drafted, SB 987 would potentially eliminate the use of AI even in simple rules-based automated systems. While it may be appropriate for the legislature to address the extent to which AI can appropriately play a role in connection with the performance of utilization review functions, the bill as currently drafted is overly broad.

In conclusion, TechNet is concerned that without changes, this bill’s broad registration framework, coupled with the potential for high fines, could hinder AI healthcare software and restrict innovation in Maryland. We hope to work with the sponsor on changes to narrow the bill’s application and set further parameters as to how the registration process would operate. Thank you for allowing TechNet the opportunity to comment and please don’t hesitate to reach out with any questions.

Sincerely,

Margaret Durkin

Margaret Durkin
TechNet Executive Director, Pennsylvania & the Mid-Atlantic

RadNet response SFC SB987 Artificial Intelligence_

Uploaded by: Michael Mabry

Position: UNF



Leading Radiology Forward

10461 Mill Run Circle, Suite 1020
Owings Mills, MD 21117

TO: The Honorable Pamela Beidle, Chair
The Honorable Antonio Hayes, Vice Chair
Members, Senate Finance Committee

FROM: Steve Forthuber, President Eastern Operations

DATE: February 25, 2025

RE: **Unfavorable:** Senate Bill (SB) 987: *Artificial Intelligence – Health Software and Health Insurance Decision Making*

RadNet leads the nation in outpatient diagnostic imaging services with nearly 400 centers in eight states. RadNet has a major presence in Maryland and our Eastern Operations are headquartered in Baltimore. You may know us locally as Advanced Radiology, Community Radiology Associates, and American Radiology Associates with over 60 imaging centers throughout the state. RadNet's digital health division, DeepHealth, is a global leader in breast, lung, and prostate cancer screening artificial intelligence (AI)-enabled software.

SB987 would: (1) require the Maryland Health Care Commission to maintain a registry of AI health software that may be distributed or operated in the State, (2) prohibit a person from distributing or operating AI health software unless the software is registered with the Commission, and (3) prohibit a health insurance carrier from using AI to decide or directly influence a health care decision or a decision directly related to health care.

AI will be a "game-changer" in radiology; perhaps the greatest opportunity for value-based care in our specialty. AI technologies are enabling the earlier detecting diseases, like cancer, than traditional methods. Screening exams are the force behind radiology's contribution to population health. AI-enabled imaging-based cancer screening will further enhance diagnostic accuracy, detect cancer sooner, and lower costs. When cancer is detected at its earliest stage, diagnostic and treatment costs are greatly reduced. In our current practice, imaging AI is helping to deliver early cancer detection while reducing costly false-positive exams and subsequent follow-up imaging ("call-backs"). Every stakeholder in the screening process -- patient, provider, and health system -- wins.

Healthcare AI in medical devices is sufficiently regulated. AI-enabled clinical technologies intended for patient use require approval by the Food and Drug Administration (FDA) just like any other medical device. The FDA has reasonable safeguards in place to ensure that clinical AI solutions perform as intended for all patients. To date, the FDA has approved over 1,000 AI-enabled medical technologies. With the AI-enabled clinical technologies in use today, there is a clinician in the "loop" who decides how to utilize the information in that patient's care. SB987's proposed registry and penalties could have a chilling effect on AI innovation and clinical adoption in Maryland.

In conclusion, Maryland is leading the nation in ensuring that all Marylanders have access to innovative cancer screenings and preventive health services, many of which utilize AI technology. SB987's proposed registry and penalties could stifle this innovation. RadNet appreciates the opportunity to provide this statement before Senate Finance Committee.

AdvaMed_MD_SB987 Testimony&Materials.pdf

Uploaded by: Roxy Kozyckyj

Position: UNF

February 27, 2025

Senator Pam Beidle, Chair
Senator Antonio Hayes, Vice Chair
3 East Miller Senate Office Building
Annapolis, Maryland 21401

RE: SB 987 – Artificial Intelligence – Health Software and Health Insurance Decision Making

Chair Beidle, Vice Chair Hayes, and Members of the Committee,

On behalf of AdvaMed, the MedTech Association, I am writing to express our concern with and opposition to SB 987. While the intent of the bill aims to understand what AI is used in healthcare in the state, the methods outlined in the bill would not achieve that end. Having manufacturers register with the state provides no meaningful information on utilization or patient population. FDA-regulated devices that are AI/ML enabled are already subject to a review of the safety and effectiveness of their locked algorithms. Creating additional barriers at the state level won't provide meaningful data for physicians, nor added protections for patients and instead create confusion and a barrier to accessing life-saving innovative care. To avoid duplicative regulation and risk to continued patient access of life-saving medical technology, we request an exemption for artificial intelligence systems subject to FDA regulation.

Artificial Intelligence (AI) advancements in the medtech industry play a major role in improving patients' lives through innovative care, reduced healthcare costs, and improved patient outcomes. Unlike many other industries, the use of AI in medical technology is already subject to strict regulation by the FDA, which includes among its submission criteria the assessment of the mitigation of unwanted bias. Additional state regulations could negatively impact the use of AI for patient care and would likely provide no additional protections for patients.

AdvaMed is the largest medical technology association, representing the innovators and manufacturers transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our nearly 500 members range from emerging companies to large multinationals, and include traditional device, diagnostic, medical imaging, and digital health technology companies.

The emergence of AI and machine learning (ML) is transforming every sector, from retail and finance to transportation. Despite its recent emergence in public



consciousness, AI is not a new concept to the Food and Drug Administration (FDA) or the medical technology (medtech) industry. Over the last 25 years, the FDA has reviewed and authorized more than 700 AI/ML medical devices – a number that continues to grow.

Today, more than 80% of in-market medical technology products utilizing AI/ML perform diagnostic functions to assist clinicians in decision-making. Predominantly, these devices do not make independent decisions on diagnoses or treatment pathways; rather they provide the clinician with better data and imaging results. Further, the FDA reviews include analysis of adequate mitigation of unwanted bias and performance of the device and algorithm.

Additionally, most AI/ML-enabled medical devices are cleared or approved with “locked” algorithms. While these devices collect data that will improve the algorithm for a new FDA review, the devices are not reacting to data and generating independent or changing outputs. Notably, any algorithm modifications must be approved by the FDA and the FDA’s post-market monitoring tools. Just as adverse event reporting and proscribed surveillance of medical devices, these requirements provide additional transparency.

AI decisions or actions (i.e., those that do not include a human in the loop) vs. decisions or actions that are augmented by AI tools as each type carries different risk considerations. We advocate for a risk-based approach to rule-making that calibrates requirements and oversight in accordance with the risk considerations for the subject of the rule. FDA follows a risk-based approach to the regulation of medical devices. As it stands today, all FDA authorized AI/ML-enabled devices are “locked” algorithms and include a “human in the loop” when making treatment decisions based on the output of an AI-enabled device.

An exemption for FDA regulated devices will help avoid unnecessary confusion, duplicative regulation, and ensure patient access to lifesaving medical technology is not impeded. AdvaMed appreciates the opportunity to comment on this legislation and looks forward to the continued dialogue and refinement.

Sincerely,



Roxy Kozycky
Senior Director, State Government and Regional Affairs
AdvaMed



Artificial Intelligence in Medtech

The emergence of artificial intelligence (AI) and machine learning (ML) can be seen across multiple industries, transforming everything from healthcare to transportation. Artificial intelligence has been in the spotlight recently, but it is not a new concept to the Food and Drug Administration (FDA) or the medtech industry. AI/ML-enabled devices are subject to the same risk-based classification paradigms for standard medical devices. AI/ML devices are evaluated to performance and safety standards commensurate to the device risk. AI advancements in the medtech industry are playing a major role in improving patients' lives through innovative care, reduced healthcare costs, and improved patient outcomes.

AI/ML Enabled Medical Devices ARE Regulated by FDA

25+ years of experience reviewing and authorizing AI/ML-enabled medical devices at the FDA.



950 AI/ML-enabled medical devices have been reviewed and authorized by the FDA since 1995, and the list continues to grow.* The process for reviewing AI/ML-enabled devices is the same as for all other medical devices.



The majority of all AI/ML-enabled medical devices are 510k cleared devices, meaning they are substantially similar to devices already in the market, and do not pose a high risk to patients or consumers.



Today's AI/ML products are largely utilized as tools used by clinicians and patients to augment decision making. Predominantly, these devices are not making independent decisions on diagnoses or treatment pathways; rather they provide the clinician with data and imaging results.



FDA reviews include analysis of adequate mitigation of unwanted bias and performance of the device and algorithm.



All AI/ML-enabled medical devices are cleared or approved with "locked" algorithms. This means the algorithms are not continuously learning or automatically evolving in the field. Modifications to the algorithms are subject to regulatory oversight.



Any algorithm modifications must be approved by the FDA. The FDA must authorize significant algorithm modifications. Predetermined Change Control Plans allow for more rapid device modifications to meet patients' needs while still maintaining strict FDA oversight.



The FDA's postmarket monitoring tools include adverse event reporting and recall authority. Device makers also have post-market responsibilities. The existing authorities and responsibilities provide sufficient checks and balances.

Keeping Health Care Costs Low

- AI/ML serves as a valuable tool for providers, helping to mitigate the impact of workforce shortages and improve overall efficiency in healthcare delivery.
- Imposing additional burdensome oversight and reporting requirements on AI/ML-enabled medical devices provides no added value or new protections for patients and consumers and instead could increase costs for patients.
- Companies would be forced to spend more time on duplicative reporting and less time developing new lifesaving technologies. This would stifle innovation and reduce patient access.

Examples of AI / ML-Enabled Medical Devices



CT scanners



MRI devices



PET scans



Image reconstruction tools



MRI devices



Surgical planning tools



Cardiac monitors

Bottom Line

AI/ML technology benefits patient care. AI/ML-enabled medical devices have been around for decades and have been heavily regulated by the FDA since inception. Imposing additional state regulation could risk compliance with the FDA and result in layers of onerous oversight that lack any meaningful benefit to patient safety or access.



Artificial Intelligence in Medical Technology Myths vs. Facts



Artificial intelligence (AI) and its subset, machine learning (ML), are expanding in multiple applications, including medical technology. Outlining the facts and dispelling myths will inform policymaking to avoid overlap with current regulations and preserve the broad capacity of innovation to help patients.



Myth: The use of AI/ML technology is unregulated and new to medical devices.

Fact: FDA has been reviewing and authorizing AI/ML-enabled medical devices for nearly 30 years. [FDA](#) approved the first medical device incorporating AI/ML technology in 1995. To date, FDA has authorized more than 500 AI/ML-enabled medical devices. Most of these devices are radiology devices (e.g., image analysis), but there are authorized devices in other medical specialties such as cardiovascular and neurology.

AI/ML-enabled devices are subject to the same premarket regulatory pathways and FDA regulatory oversight as all other medical devices. FDA assesses the safety and effectiveness of AI/ML algorithms, considering factors like data quality, robustness, and clinical performance. The majority of the FDA-authorized AI/ML-enabled devices were cleared through the 510(k) pathway for lower- and medium-risk devices. Post-market regulations and requirements also apply (e.g., adverse event reporting, quality control systems).

The FDA and the medical device industry recognize the value of globally harmonized approaches to the regulation of AI/ML-enabled devices. In 2021, the FDA, Health Canada, and the U.K.'s Medicines and Healthcare products Regulatory Agency (MHRA) jointly issued a document identifying 10 guiding principles that can inform the development of Good Machine Learning Practice (GMLP). GMLP supports the development of safe, effective, and high-quality artificial intelligence/machine learning technologies that can learn from real-world use and potentially improve device performance.

In October 2023, the agencies also issued a [joint document](#) on the use of predetermined change control plans (PCCPs) to manage certain device changes where regulatory authorization before marketing is typically required. The medical device industry and regulatory bodies recognize PCCPs as a means to manage risks in a timely, ongoing fashion through monitoring, maintenance, and/or improving device performance.

Companies also are developing their own [AI training models](#) incorporating ethics, transparency, and accountability.

Myth: AI-enabled devices introduce the potential for fake results in important patient scans.



Fact: AI in medical devices does not look or operate anything like the AI chat-bots or other “unlocked” AI algorithms that have received media attention. The type of AI attracting attention for inaccurate or faked content is “[generative AI](#),” which generates new content from data without repeating the data. For example, generative AI can be used to produce a piece of [art](#) that might resemble classic art but is brand new.

Most AI-enabled devices were cleared or approved with “locked” algorithms. This means that once the FDA has authorized the marketing of the device, it cannot be modified without FDA review and authorization. If a device manufacturer intends to modify the algorithm (e.g., based on real-life use and/or new data), the FDA would need to review and authorize the modified algorithm before it could be marketed. To date, FDA has not authorized any device that uses generative AI or artificial general intelligence (AGI) or is powered by large language models.



Myth: AI will replace doctors, nurses, radiographers, and other highly trained practitioners.

Fact: AI will not replace people. AI-enabled technology is a tool to support clinicians and improve patient care, like any other piece of technology in a medical toolkit. The technology already is enabling better understanding of diseases and faster, accurate results, helping doctors diagnose injury and illness and propose appropriate treatment. Clinicians determine their practice of medicine. They decide whether to use AI-enabled technology, as with any medical device.

AI also is being used to help make the delivery of healthcare more efficient and accessible. For example, AI-enabled software is used in some hospitals to optimize the efficient scheduling of operating rooms. Technology enabling clinicians to see more patients in less time with fast, accurate results helps patients and the entire health care system. AI could mean less time for patients in a waiting room.

The current most frequent use of AI in radiology is important because more than 80 percent of all health system visits include an imaging exam, most commonly an X-ray. AI-enabled X-rays, for example, can promote high quality services and expand healthcare access for rural and underserved populations.

Similarly, AI-based platforms can help clinicians “seeking tools that can address issues related to access, burnout, variability, equity, and cost in breast imaging to elevate and enhance the detection and diagnosis of breast cancer.”

Researchers are using AI to gain insights into diseases, with the goal of improving diagnoses and treatment. For example, a recent deep learning study identified patterns and processes to help researchers better understand how chronic obstructive pulmonary disease causes inflammation.

Congressional hearing witnesses agreed AI could reduce administrative tasks, freeing up physician time and potentially easing physician shortages, especially helpful in rural and underserved areas.



Myth: AI will benefit only well-funded, elite hospitals and medical practices.

Fact: AI can facilitate and promote access to health care in rural and other underserved communities. The technology is enabling better accuracy of equipment that innovators simultaneously are making lightweight and flexible such as magnetic resonance imaging devices and multiple clinical applications in a single platform. These innovations make critical technology more accessible to more health care facilities.



Myth: AI-enabled devices will perpetuate bias, harming patients.

Fact: When considering “bias” in AI/ML-enabled medical devices, it’s important to recognize that not all bias is “bad bias.” In some cases, algorithms may be developed with deliberate bias to optimize the device for the intended population (e.g., devices intended for a geriatric population).

FDA's review of AI/ML algorithms in devices includes an assessment to ensure unwanted bias is adequately mitigated. The technology relies on data sets to build, train, and tune algorithms. Large datasets facilitate robust algorithm development and can help identify and mitigate unwanted bias. For example, AI could interpret data to help practitioners understand physiological, natural bias, such as stroke and heart attack symptoms presenting differently in men and women, and reduce technology-related errors, such as device limitations over darker skin tones.

Terms, Defined:

The medical device industry, developers of consensus standards, and regulators are working to develop standardized terms and definitions. These definitions are verbatim from current FDA [resources](#):

Artificial Intelligence has been broadly defined as the science and engineering of making intelligent machines, especially intelligent computer programs (McCarthy, 2007). Artificial intelligence can use different techniques, including models based on statistical analysis of data, expert systems that primarily rely on if-then statements, and machine learning.

Machine Learning is an artificial intelligence technique that can be used to design and train software algorithms to learn from and act on data. Software developers can use machine learning to create an algorithm that is 'locked' so that its function does not change, or 'adaptive' so its behavior can change over time based on new data.

Some real-world examples of artificial intelligence and machine learning technologies include:

- An imaging system that uses algorithms to give diagnostic information for skin cancer in patients.
- A smart sensor device that estimates the probability of a heart attack.

Sources:

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SB0987 – Artificial Intelligence - Health Softwar

Uploaded by: Jake Whitaker

Position: INFO



Maryland
Hospital Association

Senate Bill 987 - Artificial Intelligence - Health Software and Health Insurance Decision Making

Position: *Letter of Information*

February 27, 2025

Senate Finance Committee

MHA Position:

On behalf of the Maryland Hospital Association's (MHA) member hospitals and health systems, we appreciate the opportunity to submit a letter of information on Senate Bill 987. SB 987 requires the Maryland Health Care Commission to maintain a registry of AI health software used in the state. Additionally, it prohibits the distribution or operation of such software unless registered with the Commission.

While oversight is important, we are concerned that SB 987 may slow innovation, discouraging AI developers from introducing new technologies in Maryland. Delays in approval could reduce hospital competitiveness and limit patient access to life-saving tools. Additionally, registration costs will likely be passed on to health care providers, increasing financial strain and potentially raising patient care costs.

We recommend clarifying key terms such as "health care software" to ensure a clear understanding of what technologies fall under this mandate. A lack of precise definitions could create confusion and unintended regulatory burdens on providers using standard digital tools in clinical settings.

MHA urges careful consideration of these impacts. We remain committed to working with the legislature to balance patient safety with innovation and efficiency. Thank you for your attention, and we look forward to continuing the dialogue.

For more information, please contact:

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