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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 Kozyckyj
Senior Director, State Government and Regional Affairs
AdvaMed

AdvaMed
The MedTech Association

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.

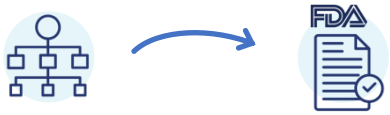
950 AI/ML-enabled medical devices have been reviewed and authorized by the FDA since 1995, and the list continues to grow.* The process for reviewing AI/ML-enabled devices is the same as for all other medical devices.

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.

*Source: https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-m

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:

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

https://www.fda.gov/medical-devices/medical-devices-news-and-events/cdrh-issues-guiding-principles-predetermined-change-control-plans-machine-learning-enabled-medical#:~:text=Today%2C%20the%20FDA%2C%20Health%20Canada,foundation%20for%20PCCPs%20for%20Machine

https://www.linkedin.com/posts/janbeger_rsna23-activity-7134624013141581824-iHmi/?utm_source=share&utm_medium=member_android

https://daily.jstor.org/ai-and-the-creative-process-part-one/

https://www.gehealthcare.com/insights/article/ai-in-xray-increasing-quality-assurance-and-workflow-efficiencies

https://www.gehealthcare.com/en-my/insights/article/expanding-imaging-ai-to-resourcestrapped-areas

https://www.gehealthcare.com/about/newsroom/press-releases/ge-healthcare-releases-mybreastai-suite-to-support-clinicians-in-accelerating-breast-cancer-detection

https://www.linkedin.com/posts/copd-foundation_copd-copdgene-deeplearning-activity-7125857620594233344-DrD7/?utm_source=share&utm_medium=member_desktop

https://energycommerce.house.gov/events/health-subcommittee-hearing-understanding-how-ai-is-changing-health-care

https://www.philips.com/a-w/about/news/archive/standard/news/press/2023/20231128-philips-launches-ultra-lightweight-and-flexible-mr-smart-fit-coils-to-improve-radiology-productivity-and-diagnostic-confidence-at-rsna23.html

https://www.mobihealthnews.com/news/rsna-philips-announces-ai-enabled-additions-imaging-portfolio

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device