AI Policy Packet

Leveraging AI to Impact and Improve Patient Lives

AdvaMed
The MedTech Association

A Message from Our President & CEO

Dear Members of Congress,

An MIT report (1) put artificial intelligence (AI) in the same category as the steam engine, the internal combustion engine, electrification, and computers — once-in-a-generation emerging technology with the power to transform economies and societies. Medical technology is experiencing exactly that transformative power. AI-enabled medical devices are both the current and next frontier in medtech, with the potential to improve the patient experience from start to finish. Already, AI-enhanced medtech is making a difference.

The American Medical Association identified (2) current and future clinical use cases of AI in medicine, in numerous categories, from cardiology to pediatrics to radiology. The AMA also identified important non-clinical uses, current and future: optimizing scheduling to minimize patient wait times; and predicting hospital staffing volumes and needs.

AI-enabled medtech can diagnose a disease or condition earlier, when diseases are more treatable, more accurately; serve as an enhancement to a clinician's expertise in interpreting results; help the clinician develop individualized treatments; and minimize the time patients spend in the doctor's waiting room for treatment. All of that means better patient experiences and outcomes at reduced cost.

The future of AI applications in medtech is vast and bright. It's also mostly to be determined, and that's a good thing. We're in an era of discovery. We can't possibly predict all the ways brilliant engineers, scientists, and clinicians will devise to use AI to improve medicine and health care. These experts continually take inspiration from patients, from successes and shortcomings, to build new models and processes.

What we can do is take care in policymaking. Too much regulation, or inconsistent regulatory oversight, stalls the development of innovative medtech. Too little policy support, and lack of reimbursement for safe, proven technology, and patients will not have access to the benefits AI-enabled devices can provide.

That's why the following policy recommendations are meant as a starting point, not a closed book. While none of us can anticipate all the change-making applications of AI in medtech to come, we can confidently predict that transformation will continue at a rapid pace. This is the right time to promote the development of AI-enabled medtech to its fullest potential to serve all patients, regardless of zip code or circumstance.

The medtech industry looks forward to continuing to work with Congress on these exciting advancements.

Sincerely,

Scott Whitaker
President and CEO
AdvaMed
The Medtech Association

Introduction

While artificial intelligence is generating headlines, its application in medical technology is not new. The FDA has more than 25 years of experience reviewing and authorizing AI-enabled medical devices. The FDA has authorized more than 1,000 such devices, including medical imaging analysis tools, blood loss estimation tools to detect maternal hemorrhages, and cardiac monitors. The list continues to grow. These advanced products can enable clinicians to better understand diseases, achieve faster, more accurate diagnostic results, and determine appropriate treatment pathways.

AI-enabled medical devices are subject to the same FDA regulatory oversight as all other medical devices. FDA's review of premarket submissions includes a rigorous assessment of the safety and effectiveness of AI algorithms, with consideration of factors like data quality, mitigation of unwanted bias, and device performance for the intended patient population. FDA's oversight extends to the post-market part of the device's lifecycle (i.e., after the device is authorized to be marketed). AI-enabled devices are subject to the substantial post-market regulations and requirements imposed on all medical devices, including adverse event reporting and adherence to quality systems regulations.

Used appropriately and supported by smart policy, AI-enabled medical devices can help ease longstanding concerns in health care by enabling clinicians to better understand diseases, achieve faster and more accurate diagnostic results, and leverage significant amounts of data to develop appropriate treatment options and care plans.

For example, AI-enabled devices help clinicians and patients in numerous ways:

Improve Disease Diagnosis

- Assess medical images derived from CT, MRI, PET, ultrasound, or other scans for clinical information, including suspected abnormalities, that may not otherwise be detectable.
- Analyze pathology samples for difficult-to-detect clinical findings.
- Assist in making informed treatment decisions by analyzing patient data, medical literature, and treatment guidelines, reducing errors, managing data burden, and improving overall clinical decision-making.

Enable Better Treatment

- Analyze complex genomic data, identify genetic markers, and uncover patterns associated with specific diseases or treatment responses, leading to more personalized and targeted therapies.
- AI and ML are being integrated into robotic surgical systems, providing enhanced precision, stability, and control during complex procedures.
- AI-powered assistive technologies, such as exoskeletons and prosthetics, can aid in rehabilitation and improve the quality of life for patients with disabilities.
- Personalizing treatment plans by identifying an optimal radiation dose, based on a tumor's size and location. AI-powered solutions can augment clinical knowledge, with the potential to improve outcomes.

Expand Patient Access to Innovative Technologies

The deployment and use of AI-enabled and digital health technologies by clinicians and health care providers can be extended to improve access to care in rural and underserved patient communities.

The expansion and extension of these technologies can bring otherwise inaccessible clinical expertise to unique populations, while better supporting clinician workload management to engage, diagnose, and treat larger volumes of patients outside of the clinical environment. Expansion of these technologies will allow clinicians to see more patients.

The continued emergence of more sophisticated diagnostics and therapy solutions, such as prescription digital therapeutics, deliver remote solution opportunities to significantly impact health equity challenges.

These uses could not only lead to more access to high quality health care and better patient outcomes but also could advance preventive care. These technologies have the power to influence:

1) changes in the care delivery paradigm;
2) the velocity to move through acute facilities with higher outcomes; and
3) managing diseases with effectiveness to reduce costs.

Examples of FDA-authorized AI-enabled Innovations Serving Patients

- An AI-based software to assist in the detection of prostate cancer in digital images of core needle biopsy specimens acquired from patients with known or suspected prostate cancer.
- AI-based software to aid in the detection and triage of acute pulmonary embolism in CT angiography images. It identifies and highlights regions of interest, alerting radiologists to suspected positive cases.
- An AI-based reading tool designed to aid endoscopists in detecting colonic mucosal lesions (such as polyps and adenomas) in real time during standard white-light endoscopy examinations of patients undergoing screening and surveillance endoscopic mucosal evaluations. It identifies and highlights regions of interest, alerting endoscopists to suspected lesions.
- An autonomous AI system is designed to detect diabetic retinopathy, including macular edema, in adults diagnosed with diabetes. It analyzes retinal images and provides a screening decision without the need for a clinician to interpret the image or results.
- AI diagnostic software as a medical device for self-administered, continuous, noninvasive, and cuffless blood pressure monitoring at home. It uses a wearable and proprietary nanotechnology that collects millisecond-by-millisecond dynamically changing physiological data — ECG, heart sounds, and thoracic impedance as inputs to the AI, which passively delivers systolic and diastolic blood pressure every 60 seconds. These devices leverage AI and machine learning to enhance the accuracy, efficiency, and consistency of diagnostic and treatment decision-making by clinicians.
- A fifth-generation multiport robotic system designed to enhance surgical precision and efficiency. It includes over 150 enhancements such as improved accuracy, next-generation 3D display and image processing, and first-of-its-kind force-sensing technology.
- A robotic-assisted solution for uncompartmentalized knee arthroplasty procedures. The robotic assistance improves surgical outcomes.
- A spine analyzer intended for assisting clinicians in viewing and measuring spine-related X-ray images as well as planning orthopedic spine surgical procedures. The device also includes tools for measuring anatomical components for placement of surgical implants.
- Insertable cardiac monitors, with embedded algorithms for arrhythmia monitoring and detection, that leverage two cloud-based AI algorithms to improve diagnostic specificity by rejecting false atrial fibrillation and pause episodes from patient ECGs, reducing clinical data review burden.

An Example of an Application Apart from FDA Oversight, Useful to Medical Practice

- An ambient clinical intelligence solution using AI to securely capture and contextualize physician-patient conversations during virtual or in-person visits. It automatically creates detailed clinical notes, reducing the administrative burden on providers and improving data capture accuracy.

POV: AI and Patient Stories

Faster Care for Strokes, Aneurysms, and Embolisms

A company called RapidAI developed technology to get faster care to stroke victims. The technology has been used for aneurysms and pulmonary embolisms as well, now deployed in more than 2,000 hospitals in more than 100 countries. Examples of how the technology has helped patients:

29-Year-Old Stroke Victim

> One is a young patient, a 29-year-old firefighter and paramedic with no known pre-existing conditions, who suffered a stroke while working out.
>
> The neuro-interventional team was alerted, so when the patient arrived at the hospital, a CT scan was performed, and an automated notification was sent to the team as soon as the scan results were available. The scan revealed the need for an immediate mechanical thrombectomy (a clot-retrieval procedure that would remove the blood clot causing the stroke).
>
> Because of our technology, the entire team was ready to go right away, and the patient received immediate treatment, restoring blood flow in under 60 minutes.

Boy With Metal Straw Brain Injury

> Our software has even been used to help treat medical emergencies outside the realm of traditional neurovascular and vascular conditions. There was a recent story of a boy who had been impaled by a metal straw, which struck an artery in his brain.
>
> One of our modules, which is typically used to look for salvageable brain tissue, was used to ultimately determine that the patient's carotid (which compromised the entire right hemisphere) was severely hypoperfused [decreased blood flow]. The doctors used this information to guide treatment decisions and save the boy's life." (3)

Following are areas for policymaker consideration to help promote the accessibility and use of AI-enabled medical devices to serve patients.

Privacy & Data Access

Background

AI is distinguished from other health technologies by its ability to analyze vast datasets to assist physicians in diagnosis and treatment, supplement and enhance the clinical process, and offer personalized health care solutions. AI can provide insights that may not otherwise be available via conventional health care technologies or techniques and rapidly process data to produce clinical support and recommendations that can be used to inform care decisions.

Large, diverse data sets are needed by AI medical device developers to train and validate trustworthy algorithms. Unlocking the potential of AI-driven health care solutions is linked to the availability of high-quality data to build and evaluate these technologies. Challenges such as the fragmented nature of health care data, non-standardized data formats, difficulty accessing data across different health systems, and the lack of interoperability between platforms impede the pace of innovation. Flexibility to pursue different approaches to obtaining and utilizing data is crucial to ensuring innovation is not limited by data access.

Data aggregation and access processes are currently siloed and complex to navigate. This work is spread across many different data aggregators and third-party data vendors whose data is not standardized, leading to disparate data quality and utility. Additionally, there are only a handful of commercial vendors that provide the services needed to link data (e.g., tokenization and expert determination).

In undertaking data collection, it is crucial to address the data protection requirements for the large-scale processing of health data that powers AI models. Safeguarding patient privacy and ensuring robust data security are vital to protecting sensitive health information. Moreover, informed notice and patient autonomy are important to meaningful patient involvement in AI-driven health care decisions.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) is a federal law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge. These regulations impose strict requirements on the collection, storage, use, and disclosure of patient health data, making it difficult for developers to access and utilize large-scale datasets with intact metadata.

Data quality and provenance are important considerations for AI medical device developers in the training and validation of AI models. Privacy law requirements for de-identification and/or minimization of personal data or metadata can be inconsistent and at tension with these important considerations. These inconsistencies impact the ability of AI medical device developers to:

- access, store and retain training and validation datasets (and metadata) over a certain period of time to meet FDA's recommendations; and
- demonstrate that the dataset used to train and tune the device is robust and representative of the intended patient population. To conduct a bias analysis, for example, patient demographic and health information may be required (e.g., ethnicity, sex, gender, age, and any relevant clinical indications). This information can be hard to obtain, or it may be difficult to negotiate retention periods or data use rights.

Policy Recommendations

Recommendation: Ensure data protection without stifling innovation.

Develop pragmatic data regulations for AI in health care that promote the development of privacy-preserving AI techniques to balance innovation and the development of AI solutions with the need to protect sensitive health data.

Recommendation: Evaluate the need to update HIPAA for the AI era and create clear guidelines specifically for data use in AI development.

Ensure that HIPAA standards allow for the sharing of the datasets needed to train, test, validate, and re-train AI models while preserving patient privacy. The current HIPAA de-identification methods (authorization, safe harbor, and expert determination) stifle the high-volume data usage and sharing that can optimize the development of safe and accurate AI models.

Recommendation: Develop appropriate guidelines around patient notice and authorization for the data used to develop AI.

More data will allow for the creation of better, more accurate AI models. Patient notice and authorization should be at the center of additional data accessibility. New frameworks for health data regulation should consider any data limitations presented by HIPAA and other privacy laws.

Benefit to Patients

AI-enabled devices can help clinicians detect abnormalities—whether tumors, fractures, aneurysms, or other conditions—that may not have been previously detectable. AI is improving patient experiences by reducing MRI scan time. AI-enabled camera technology can automatically detect anatomical landmarks in a patient, thereby enabling fast, accurate, and consistent patient positioning and reducing the patient's exposure to radiation. In cardiology, AI-enabled electrocardiogram diagnostic software enables faster diagnoses of heart disease.

Benefits can include:

- achieving more accurate diagnoses via algorithms that improve detection, characterization, monitoring, and therapeutic treatment of disease;
- reduced time to diagnosis and initiation of an appropriate care pathway;
- more precise direction to appropriate sites of service that offer optimal care pathways;
- lower patient radiation and contrast doses through optimization and management algorithms; and
- reduced errors and redundant tests.

Robust datasets also improve efficiencies and improve workflows in clinical settings on tasks including generating documents, scheduling patient and clinical tasks, and allocating staff resources where most needed. These applications could lead to shorter wait times for clinical services, more time for patients with their clinicians, and better written explanations of medical findings and after-care instructions.

POV: AI and Patient Stories

Patient Regains Her Voice

AI has enabled a paralyzed woman to speak for the first time in 18 years by using a digital copy of her recorded voice.

The woman, named Ann, who has been unable to communicate verbally for nearly two decades, can now express herself thanks to cutting-edge brain-computer interface (BCI) technology.

Developed by a team of researchers including Dr. Edward Chang of UC San Francisco, this innovative technology translates Ann's brain signals into text, speech and facial expressions for a digital avatar.

This breakthrough has the potential to greatly improve communication for paralyzed people. (4)

FDA AI Regulatory Framework

Background

FDA has a comprehensive regulatory framework that ensures the safety and effectiveness of many different types of medical devices across the product's lifecycle. FDA's oversight is guided by a risk-based framework that includes a rigorous premarket review process as well as extensive post-market monitoring requirements after devices are authorized for sale. FDA's regulatory frameworks are able to accommodate emerging technologies in medical devices, such as AI.

FDA has been regulating AI-enabled medical devices for over 25 years. As of December 20, 2024, the FDA has authorized over 1,000 AI-enabled devices using the same regulatory paradigms and the same rigorous review processes as for other regulated medical devices. The FDA's premarket review includes, among other considerations, an assessment of the safety testing and performance validation conducted by device manufacturers, an assessment of the conducted risk analysis, and an assessment of the mitigation of unwanted bias for the intended patient population. The FDA's regulatory oversight continues in the post-market part of the device's lifecycle, with requirements for manufacturers to conduct ongoing monitoring and reporting of device performance and safety to mitigate risks and ensure compliance with regulations.

In 2022, Congress passed predetermined change control plan (PCCP) legislation. PCCP is an innovative concept that provides a voluntary pathway for industry to obtain review and authorization from FDA of pre-specified changes to a device in a premarket submission. The PCCP framework permits a manufacturer to make controlled changes or updates to a device in accordance with the FDA-authorized PCCP without needing to submit a new premarket submission to FDA. The PCCP authority enables manufacturers to innovate more efficiently and rapidly to help improve patient health while still ensuring the safety and effectiveness of the device. The PCCP framework has great applicability to all medical devices. For AI-enabled devices, in particular, it enables the regulatory framework to keep better pace with the rapid innovation inherent to AI, thereby ensuring clinicians and patients have timely access to improved devices.

Expectations for both the pre- and post-market have been outlined by FDA in its draft guidance, "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations."

Policy Recommendations

Recommendation: FDA should remain the lead regulator responsible for overseeing the safety and effectiveness of AI-enabled medical devices.

As discussions about oversight of AI technologies across industries continue to evolve, it is crucial to distinguish between the different applications of AI (e.g., medical devices versus self-driving cars) and ensure that regulations are appropriately tailored to the respective uses and needs. The challenges and opportunities presented by AI differ across sectors, making it critical that FDA remain the sole regulator overseeing the safety and effectiveness of AI-enabled medical devices. Overly burdensome regulations risk stifling innovation and diminishing patient care. FDA oversight ensures that safety and performance considerations unique to AI-enabled medical devices are evaluated and implemented with the appropriate context and oversight.

Recommendation: FDA should implement the existing PCCP authority to ensure it achieves its intended purpose of ensuring patients have timely access to positive product updates.

We commend Congress for the enactment of the PCCP authority. This streamlined approach to enhance premarket efficiency is a promising example of how new and right-sized policy development can occur in response to changes in technology or regulatory needs. We also commend the FDA for issuing a guidance document on the implementation of the PCCP authority for AI-enabled devices. FDA's AI PCCP guidance is a valuable tool to promote consistent understanding and implementation of this new process. However, the guidance includes recommendations that are inconsistent with the statutory authority for PCCP.

For example, the guidance indicates certain premarket submission types are not suitable for establishing a PCCP though there is no statutory basis for this prohibition. A restrictive approach to implementation of the PCCP authority diminishes the intended efficiency to implement device improvements. We encourage FDA to authorize PCCPs that promote efficient post-market changes for AI-enabled devices.

It is also important that FDA's implementation of the PCCP framework continues to evolve as AI technology and its use in medical devices continue to evolve. If implemented with the intended flexibility, authorized PCCPs can enable the regulatory frameworks to keep pace with the rapid innovation inherent to AI.

Recommendation: FDA should issue timely and current AI guidance documents related to AI-enabled devices and to prioritize the development and recognition of voluntary international consensus.

FDA must ensure the tools and processes it has under its existing authority are implemented and, where appropriate, adapted to keep pace with emerging technologies. As AI technology matures, international consensus standards specific to medical devices should be the foundation for safe, effective, and responsible development and deployment. It is critical that FDA prioritize the development, revision, and timely recognition of such standards to promote industry-wide adoption of these best practices.

Similarly, FDA-issued guidance is a critical tool to promote transparency and common understanding between FDA and the medical device industry. A focus on ensuring international standards and FDA guidance reflect current practices would support consistency in FDA's expectations for AI-enabled medical technologies.

Recommendation: FDA should establish a globally harmonized approach to regulatory oversight of AI-enabled devices.

AdvaMed members support a globally harmonized regulatory approach for AI-enabled medical devices. AdvaMed supports the recent collaborative efforts between US FDA, Health Canada, and UK MHRA to establish a common perspective on good machine learning (ML) practices for medical device development, PCCP for ML-enabled medical devices, and transparency for ML-enabled medical devices. We encourage FDA and policymakers to consider policies and practices that support global alignment, where practical.

Benefit to Patients

The incorporation of AI technology into medical devices has the potential to greatly improve patient health outcomes and the conditions of patient care delivery. The FDA's robust regulatory framework addresses all medical devices, including AI-enabled devices, and the agency has a long, proven history of using that framework to evaluate innovative medical technology for safety and effectiveness. The FDA regulatory framework provides patients with timely access to safe and effective AI-enabled devices, enabling clinicians to provide state-of-the-art care. And the framework's adaptability, exemplified by the Predetermined Change Control Plan option, enables the FDA to ensure that updates to medical devices are implemented more efficiently and rapidly while maintaining device safety and effectiveness.

POV: AI and Patient Stories

Mayo Clinic Combines AI and Cardiovascular Care

Helping people who have had a stroke.

> In emergency rooms, when people come in with a stroke called an intracerebral hemorrhage, they get a CT scan. That scan is examined by a computer trained to analyze CT data. This method has been shown to cut the time to diagnosis and limit brain damage.

Preventing heart problems.

> Applying AI to ECGs has resulted in a low-cost test that can be widely used to detect the presence of a weak heart pump. A weak heart pump can lead to heart failure if left untreated. Mayo Clinic is well situated to advance this use of AI because it has a database of more than 7 million ECGs. First, all identifying patient information is removed to protect privacy. Then this data can be mined to accurately and quickly predict heart failure.

Detecting atrial fibrillation (AFib) sooner.

> AI-guided ECGs also are used to detect faulty heart rhythms before any symptoms are evident. A faulty heart rhythm also is called atrial fibrillation. (5)

Reimbursement & Coverage

Background

Appropriate reimbursement for the adoption and use of AI-enabled devices is critical to ensuring patients have timely access to and benefit from these innovations. As the nation's largest payer of health care, Medicare's policies on coverage and payment for AI technologies are especially critical, applying to the millions-strong Medicare population, and because private payers and state Medicaid plans often look to Medicare as they establish their own coverage policies.

We believe Medicare has regulatory authority to expand access to AI technologies. However, its regulatory framework currently lacks the specificity and clarity to provide coverage and payment for digital health technologies broadly and for AI and software specifically. The result has been incremental, technology-specific policy changes, with many AI and software innovators struggling to find pathways to coverage and reimbursement for new technologies.

There is no "one size fits all" reimbursement policy for every AI technology. Instead, appropriate payment mechanisms vary depending on the kind of technology in question and the clinical setting in which it is used. Regardless, accurately capturing the cost and value of these technologies is critical to ensuring appropriate reimbursement.

Policy Recommendations

Recommendation: Consider legislative solutions to address the impact of budget neutrality constraints on the coverage and adoption of AI technologies.

Generally, Medicare's payment systems are required to maintain budget neutrality while developing new payment and coverage policies. These requirements and others like it have a significant impact on Medicare's ability to expand coverage for and support the adoption of new technologies, including AI technologies, because the funding for these expansions comes at the cost of other services under the same payment system.

We urge Congress to consider legislative solutions to address the impact of budget neutrality constraints on the coverage and adoption of AI technologies.

Recommendation: CMS should develop a formalized payment pathway for algorithm-based health care services (ABHS) to ensure future innovation and to protect access to this subset of AI technologies for Medicare beneficiaries.

A subset of AI technologies is algorithm-based health care services (ABHS), which are rapidly developing and becoming increasingly important to deliver optimal patient care. ABHS are clinical analytical services delivered by FDA-authorized devices to a health care practitioner, using AI, ML, or other similarly designed software to produce clinical outputs for the diagnosis or treatment of a patient's condition. ABHS provides quantitative and qualitative analyses, including new, additional clinical outputs that detect, analyze, or interpret data to improve the screening, detection, diagnosis, and treatment of disease.

Recommendation: To ensure future innovation and to protect access to ABHS for Medicare beneficiaries, we urge CMS to develop a formalized payment pathway for ABHS.

CMS should codify in regulation its existing Software-as-a-Service (SaaS) payment policy that the agency articulated in the calendar year 2023 Medicare HOPPS Final Rule to provide stability and certainty moving forward.

Furthermore, CMS should consider modifying both the New Technology Ambulatory Payment Classification (APC) application requirements and corresponding annual payment policies to ensure they are tailored to the unique aspects of ABHS. For those ABHS that receive a New Technology APC assignment, there must be sufficient stability such that these services are not inappropriately reassigned to a different New Technology APC. These two impactful steps will lay the groundwork for increased ABHS innovation while protecting access to care for Medicare beneficiaries.

Recommendation: Facilitate the adoption and reimbursement of digital therapeutics through legislation and regulation.

Digital therapeutics are evidence-based, standalone or combination software products intended for management, maintenance, prevention, or treatment of a disease, disorder, or condition acting directly as a medical intervention or guiding the delivery of a medical intervention. Given nationwide provider shortages, these FDA-regulated medical devices can expand access to critical health services, including mental health services, where access today is limited. However, the lack of clarity on appropriate coding and payment for these products under Medicare has unnecessarily limited access to first-line treatment for many Medicare beneficiaries in need.

CMS recently extended coverage to a subset of digital therapeutics, defined by the Agency as Digital Mental Health Treatment (DMHT) devices. DMHT devices are furnished under the Physician Fee Schedule incident to professional behavioral health care treatment and under a behavioral health treatment plan of care. FDA regulations currently consider insomnia, substance use disorder, depression, and anxiety under this category. While CMS has indicated its payment for DMHT is not limited to these diagnoses, the agency continues to assert a lack of authority to cover a broader range of these technologies under its existing benefit categories.

Recommendation: CMS should leverage its model authority to test the ability of AI technologies to improve patient care and/or lower costs.

The Center for Medicare and Medicaid Innovation, also known as the CMS Innovation Center, has broad authority to test new alternative payment models promoting high-quality and cost-efficient care in the Medicare, Medicaid, and Children's Health Insurance Program (CHIP) programs. These models are intended to help accelerate the shift from a health care system that pays for volume to one that pays for value. CMS should work with providers, patients, and industry to develop a model testing the ability of AI technologies to improve patient care and/or lower costs and, if the model is successful, move toward nationwide implementation of this value-based care model.

Benefit to Patients

Medicare beneficiaries deserve access to safe, proven effective medical technology that can improve their health outcomes and meet underserved clinical needs, such as mental health services. Medicare beneficiaries stand to gain greatly from the development and adoption of digital health and AI-enabled technologies that improve the diagnosis and treatment of illness and disability, promote healthy behaviors, and support population health management. Appropriate reimbursement policies will enable doctors, hospitals, and other caregivers to adopt AI-enabled medical devices into their practices, improving the care they can give patients.

POV: AI and Patient Stories

Using Math to Predict Disease

Scientists are constantly developing new, highly complex algorithms that can identify trends or commonalities within mountains of anonymized health data. Medtronic is already using such AI in a device which helps doctors identify colon polyps that might be missed by a clinician.

Another example: Algorithms in an implantable heart monitor help doctors more accurately detect abnormal heart rhythms like atrial fibrillation (AF), which if left untreated can increase the risk of stroke or heart failure. Once diagnosed, these abnormal heart rhythm conditions can be treated with drugs or medical interventions, such as AF ablation procedures.

Next up? Advanced algorithms that can analyze heart data and identify early signs of treatable heart disease before the patients even know they're sick! (6)

AI-Guided Ultrasound: From Innovation to Impact at GE HealthCare

"AI-guided ultrasound is now a reality, transforming healthcare by democratizing access to diagnostic-quality imaging. It empowers clinicians with limited ultrasound experience to capture precise images. Combined with the rise of portable devices enabling point-of-care ultrasound (POCUS), AI scan guidance is expanding access to high-quality medical care for a broader range of patients.

AI-powered scan guidance gives operators real-time feedback during scans. Deep learning algorithms, trained on vast ultrasound data, recognize anatomical structures and guide the user on probe positioning and adjustments. This support enables consistent, high-quality imaging, no matter the experience level of the clinician performing the scan.

As POCUS utilization grows, AI-powered scan guidance supports clinicians with limited ultrasound experience to effectively utilize the modality. Improved scan accuracy can enhance the clinician's decision-making, treatment planning, and even patient transfer decisions, enabling more efficient care and better patient outcomes across various points of care." (7)

Additional Background : AI Assurance Labs

Background

FDA and other health care stakeholders are exploring the creation of third-party quality assurance labs to support AI lifecycle management in medical devices, with a focus on ongoing performance monitoring. However, concerns have arisen about the suitability and practicality of this approach.

One issue is the unclear and evolving scope of these third-party labs' roles. Given FDA's existing oversight, the utility of third-party labs for regulated medical devices is unclear. Another issue is that third-party labs may lack the contextual understanding and specific data needed to evaluate and interpret the performance of each device accurately, which could impact the reliability of their assessments.

There are also significant concerns about sensitive data. Mandating manufacturers to share proprietary information about AI-enabled devices with external labs raises confidentiality, intellectual property, and security issues. Variability in lab security practices could expose sensitive information, jeopardizing manufacturers' rights and potentially affecting patient safety.

If third-party labs were linked to the regulatory process, their use would effectively become mandatory, increasing costs and burdens for manufacturers who already evaluate their devices, often in accordance with voluntary consensus standards. The proprietary nature of some labs' methods could also limit transparency, as testing metrics and methodologies may remain inaccessible to patients and providers. These concerns underscore the need for clarity and careful consideration in assessing the role of third-party labs in AI lifecycle management.

FDA's rigorous premarket review of AI-enabled devices includes an assessment of whether the device performs as intended for the intended patient population. Once the device is on the market, medical device manufacturers must adhere to post-market monitoring and reporting requirements to ensure the device continues to perform safely and effectively in clinical use. Implementing a third-party framework of labs creates, at best, redundancy with existing FDA oversight, while potentially increasing costs, slowing innovation, and limiting access to valuable medical devices, without clear benefit to clinicians or patients.

Policy Recommendations

Recommendation: Policymakers should encourage FDA to participate in the development of and timely recognition of accredited and consensus-based standards for quality assurance processes rather than rely on third-party assurance labs.

The longstanding practice of relying on collaboratively developed, international consensus standards would support a deeper understanding of both the benefits and risks of these technologies and improve transparency. Empowering manufacturers to adhere to shared industry standards allows for robust, transparent quality assurance that maintains data security and IP confidentiality. This approach supports patient safety and innovation by minimizing the need for external assessments, which could introduce added costs, regulatory delays, and potential security vulnerabilities.

Additional Background : Generative AI

Background

Generative AI (GenAI) is a subtype of AI technology that is intended to create new content—such as images, text, or audio—by learning from extensive datasets, approximating the statistical distribution of training data to emulate its patterns. To date, there are no FDA-authorized devices that employ generative AI; however, FDA and the medical device industry recognize the technology shows promise in the health care sector, with applications such as synthesizing medical images for training and producing preliminary radiology reports.

Emerging use cases for generative AI in medical imaging and other medical applications underscore the need for regulatory flexibility. As emphasized in recent industry comments, any future regulatory approach should carefully weigh the benefit-risk profile of these devices, recognizing the FDA's existing robust framework for evaluating technology safety and efficacy throughout the product lifecycle. Compared to other types of AI, generative AI's dynamic outputs may present unique regulatory considerations. However, it is essential that all stakeholders have a common understanding of any such distinctions before implementing regulatory changes based on theoretical considerations. A practical approach to policy supports responsible innovation while safeguarding patient safety.

Policy Recommendations

Recommendation: Ensure FDA reviews and considers GenAI-enabled devices using the existing risk-based frameworks.

Existing premarket and post-market regulatory frameworks are designed to be both robust and flexible; they ensure the safe and effective use of a vast and diverse array of medical device types while allowing for innovation and advances in medical technologies. GenAI is an innovation in medical technology, but as with all medical devices, the risk profile for GenAI-enabled medical devices will vary greatly across device types and their intended uses.

FDA applies a risk-based approach to device classification that assesses the specific technological considerations, safety considerations, and intended use of each device. The existing frameworks ensure the safety and effectiveness of the device because they consider the relevant factors of the device's risks and performance holistically, rather than focusing solely on the technology that it incorporates. As use cases for GenAI emerge and evolve, any evolution of the medical device regulatory frameworks or the risk classification decisions for GenAI-enabled medical devices should be developed collaboratively and transparently with relevant stakeholders in the medical device sector.

Recommendation: Encourage FDA to maintain ongoing dialogue with stakeholders in the health care sector and regular information-sharing on generative AI applications in medical devices.

This collaborative approach would support a deeper understanding of both the benefits and risks of these technologies without imposing unnecessary regulatory requirements. By convening public meetings (such as the November 2024 Digital Health Advisory Committee Meeting), workshops, panels, and industry-led initiatives, policymakers can facilitate knowledge transfer, clarify best practices, and develop a shared framework for assessing generative AI in health care. This approach will allow regulators, manufacturers, and health care providers to align on standards, validation methods, and safety concerns while preserving the adaptability of the current regulatory framework.

Glossary of Terms

Algorithm-Based Healthcare Services: A service delivered through a device cleared or approved by the Food and Drug Administration that uses artificial intelligence, machine learning, or other similarly designed software to yield clinical outputs or generate clinical conclusions with varying physician or other qualified health care professional involvement in the screening, detection, planning, diagnosis, or treatment of an individual's condition or disease.

Artificial Intelligence (AI): A machine-based system that can, for a given set of human-defined objectives, make predictions, recommendations, or decisions influencing real or virtual environments. Artificial intelligence systems use machine-based and human-based inputs to: (A) perceive real and virtual environments; (B) abstract such perceptions into models through analysis in an automated manner; and (C) use model inference to formulate options for information or action. 15 U.S.C. 9401(3)

AI-Device Software Function (AI-DSF) and AI-enabled device: A software function that meets the definition of a medical device in section 201(h) of the Food, Drug, & Cosmetics Act (defined below) and implements an AI model.

Example: a software that incorporates an AI algorithm that is intended to enhance and analyze medical images taken from an MRI machine.

FDA uses the terms "AI-DSF" and "AI-enabled device" interchangeably in its final guidance, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions." In this document, AdvaMed uses the term "AI-enabled device" consistent with FDA. FDA-2022-D-2628

Bias: In the context of AI, bias refers to the systematic deviation in model predictions or outcomes for certain data points or groups compared to others. The nature of a system's bias—i.e., whether it is "wanted" or "unwanted"—depends upon the intended purpose of the AI-based system. [For example, for an AI-based system for the detection of leukemia, a "wanted" bias would be bias toward the detection of leukemia over other pathologies, whereas "unwanted" bias could include unintended differences in performance across different age groups in the intended patient population.] ISO/IEC TR 24027, MDRF Machine Learning-enabled Medical Devices

Device: A device is an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. Recognized in the official National Formulary, of the United States Pharmacopoeia, or any supplement to them;
2. Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals; or
3. Intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section FD&C Act Section 201(h)(1)

Digital Health Technology: A system that uses computing platforms, connectivity, software, and/or sensors for health care and related uses. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device. They include technologies intended for use as a medical product, in a medical product, or as an adjunct to other medical products (devices, drugs, and biologics). They may also be used to develop or study medical products. FDA-2021-D-1128

Digital Mental Health Treatment Devices (DMHT): In general, refers to software devices cleared, approved, or granted marketing authorization by the Food and Drug Administration that are intended to treat or alleviate a mental health condition, in conjunction with ongoing behavioral health care treatment under a behavioral health treatment plan of care, by generating and delivering a mental health treatment intervention that has a demonstrable positive therapeutic impact on a patient's health. 89 FR 97923

Glossary of Terms

Digital Therapeutic (DTx): Evidence-based therapeutic health software intended to treat or alleviate a disease, disorder, condition, or injury by generating and delivering a medical intervention that has a demonstrable positive therapeutic impact on a patient's health. Source: Digital Therapeutics Alliance

Generative AI: A system of algorithms or computer processes that can create novel output in text, images, or other media based on user prompts. Source: National Library of Medicine

FDA's final guidance, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions," affirms that devices that incorporate generative AI are considered an "AI-enabled device."

Predetermined Change Control Plan (PCCP): PCCP refers to the documentation included in an FDA marketing submission that describes the device modification(s) the manufacturer intends to make (Description of Modifications), how the modifications will be validated and implemented (Modification Protocol), and an assessment of the benefits, risks, and risk mitigation (Impact Assessment). Obtaining FDA authorization of a PCCP as part of a marketing submission promotes regulatory efficiency because it allows a manufacturer to modify the device in accordance with the PCCP instead of obtaining separate FDA authorization for each change prior to implementation.

Section 3308 of the Food and Drug Omnibus Reform Act of 2022, Title III of Division FF of the Consolidated Appropriations Act, 2023, Pub. L. No. 117-328 ("FDORA") enacted on December 29, 2022, added section 515C "Predetermined Change Control Plans for Devices" to the FD&C Act.

Software as a Service (SaaS): The capability provided to the consumer is to use the provider's applications running on a cloud infrastructure. The applications are accessible from various client devices through either a thin client interface, such as a web browser, or a program interface. The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, storage, or even individual application capabilities, with the possible exception of limited user-specific application configuration settings. Source: NIST SP 800-145 Adopted by CMS

Source links:

(1) https://tinyurl.com/29fn8vcd
(2) https://tinyurl.com/bdhar3y5
(3) https://tinyurl.com/596bxy2a
(4) https://tinyurl.com/mrfatt75
(5) https://tinyurl.com/2dyfefar
(6) https://tinyurl.com/2rhp2xch
(7) https://tinyurl.com/khuxjkpe

About AdvaMed

AdvaMed, the Medtech Association, is the world's largest trade organization representing medtech innovators. Our member companies develop, manufacture, and distribute the technologies including the devices, equipment, diagnostic tests, and imaging technology that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Based in Washington, D.C., AdvaMed has more than 600 members, operating all over the United States and world.

Our divisions are AdvaMedDx, for diagnostics companies; Accel, for emerging and early-stage companies; Digital Health Tech; and Medical Imaging. Our sectors are Radiation Therapy, Diabetes, and Orthopedic.

Our organization advocates for increased patient access to safe, effective, lifesaving, and life-enhancing medtech. This advocacy unfolds in the halls of the U.S. Congress, with federal agencies, at the White House, and in every state legislature. Medtech has a presence in every state, supporting more than two million jobs, directly and indirectly.

AdvaMed conducts its work through our main board of directors, boards for each division, and dozens of working groups on specialized topics. Company representatives interact with our advocacy and technology and regulatory expert staffs to convey the impact of policies on patients to policymakers and regulators. Together, we press for policies that promote access to medtech to every patient who could benefit from it.

For more on our recent work, please see our 2024 Annual Report.