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May 6, 2024

The Honorable Ami Bera
United States House of Representatives
172 Cannon House Office Building
Washington, DC 20515

Re: Rep. Ami Bera Request for Information on Artificial Intelligence in Healthcare

Dear Dr. Bera:

The Advanced Medical Technology Association (AdvaMed) and the AdvaMed Medical Imaging Division appreciate the opportunity to submit comments in response to your March 20, 2024 request for information (RFI) on the current state of artificial intelligence (AI) in healthcare.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies range from the largest to the smallest medical product innovators and manufacturers, with nearly 70 percent of our members generating less than $100 million in annual sales. AdvaMed's member companies produce innovations that transform healthcare through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed advocates for a legal, regulatory, and economic environment that advances global healthcare by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, timely product authorization, appropriate reimbursement, and access to international markets.

The AdvaMed Medical Imaging Division represents the manufacturers of medical imaging equipment, including, magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, and imaging information systems. Our members have introduced innovative medical imaging technologies to the market, and they play an essential role in our nation's healthcare infrastructure and the care pathways of screening, staging, evaluating, managing, and effectively treating patients with cancer, heart disease, neurological degeneration, COVID-19, and numerous other medical conditions.

We recognize AI as a transformational tool with the potential to improve health outcomes, enhance efficiency of patient care, lower costs, and make advancements in healthcare. AdvaMed's members are uniquely positioned to provide feedback on frameworks and policy considerations regarding AI-enabled tools in healthcare. Our members develop AI-enabled tools that are integrated into medical devices or are regulated as medical devices themselves, as well as standalone AI tools to support patient care.

Below, we provide high-level comments in response to the questions posed in your March RFI. For ease of review, the original section heading and questions from your letter are reiterated below in bolded italics, followed by AdvaMed's response.

Implementation

1. ***How extensively is AI currently being implemented in healthcare institutions and other settings across the country?***

   Public discussion regarding artificial intelligence (AI) and machine learning (ML) has increased in recent years as the utilization of AI/ML technology has expanded in all sectors of society. However, the utilization of AI/ML technology is not new for the medical device industry. The Food and Drug Administration (FDA) has been reviewing and authorizing AI/ML enabled medical devices for over 25 years; it has authorized approximately 700 AI/ML enabled devices as of July 2023[1]. These devices are utilized in a variety of medical specialties including radiology, cardiology, and neurology. AI is also being used to implement secure and accessible hybrid care delivery models, address healthcare workforce shortages and streamline processes with the use of non-FDA regulated AI tools (e.g., note transcription and scheduling tools). As the number of AI applications continues to grow, and their clinical importance continues to be demonstrated, it is likely that more of these technologies will be widely adopted and become the standard of care.

2. ***What areas of healthcare are benefiting the most from AI integration, and what are the primary challenges hindering further adoption?***

   AI and digital health technologies are being used across care pathways and sites of care to improve population health, enhance patient experiences, avoid unnecessary costs, and improve the experiences of clinicians and healthcare staff. Over 80% of FDA-authorized AI/ML enabled devices are used in medical imaging and radiology (e.g., medical image analysis tools). These devices utilize deep learning models and are used as adjunctive tools to support more efficient and effective clinical decision-making by, for example, identifying patterns or characteristics in medical images that are not perceptible to the human eye. AI applications are also being used to create greater efficiency in the administration of healthcare. The integration of AI into workflows enables hospital organizations to do more with less and scale their operations to better meet the needs of their community. AI-enabled tools can generate efficiencies and reduce costs by quickly analyzing large sets of data to identify trends and automating certain tasks such as document generation, patient and clinical task scheduling, and allocating staff resources where they are most needed. In a healthcare landscape suffering from acute staff shortages,[2] these applications will continue to see greater adoption and will play a vital role in enabling more efficient use of resources.

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

[2] Dzakula, Aleksandar, et. al. "Health workforce shortage- doing the right things or doing things right." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9086817/

Below are some illustrative examples of how AI-enabled tools are currently being used in healthcare and the benefits they deliver to patients and healthcare providers;

- Improving population health
    - Achieving more accurate diagnoses via algorithms which improve detection, characterization, monitoring, and therapeutic treatment of disease
    - Realizing improved image quality via advanced reconstruction techniques

- Enhancing patient experiences
    - Lower patient radiation and contrast dose through optimization and management algorithms
    - Reduced time to diagnosis and initiation of an appropriate care pathway
    - Direction to appropriate sites of service which offer optimal care pathways, improving patient outcomes

- Avoiding unnecessary costs and driving cost efficiency
    - Reducing errors and redundant tests
    - Avoiding costs of continued health decline and associated outcomes and treatment via more accurate and expedient care
    - Enhancing patient safety
    - Low-risk processes where AI enables efficiency gains (e.g., workflows, documentation)

- Improving the experiences of clinicians and healthcare staff
    - Decreasing variability in diagnostic accuracy between readers and facilities
    - Automatically annotating and evaluating images with concerning findings, allowing for more focused physician interpretation and reporting
    - Automating tasks such as dose management and patient positioning
    - Improving machine up-time via monitoring of device malfunction and servicing events

Realizing the maximum potential of AI technologies will require an alignment of policies and incentives that appropriately promote adoption and facilitate innovation. Congress and the Centers for Medicare and Medicaid Services (CMS) have an opportunity to support innovation and more widespread adoption of AI technologies in healthcare by developing sound policy in collaboration with the greater community of interested and affected stakeholders, including innovators, healthcare providers, and patients. Challenges hindering adoption and innovation include:

1. Inadequate reimbursement mechanisms, particularly in community practice. Adoption of AI technologies and realization of the benefits they offer is significantly slowed by the lack of clear reimbursement and payment policies. We recommend transparent and predictable coverage processes that have clearly-stated criteria for AI-based technologies, nimble and accurate code development processes that allow for timely recognition of new technologies as they come to market, and appropriate payment for the use of these technologies;

2. Difficulty obtaining high-quality data. Large quantities of diverse data sets are needed by algorithm developers for the development, training, and validation of trustworthy algorithms. Challenges in obtaining the necessary data impede the pace of innovation. Developers' access to data is hindered by the fragmented nature of healthcare data across different healthcare systems, providers, and platforms. We recommend implementation of policies that will promote access to quality data; and

3. The sensitive nature of healthcare data and the varied ways health data is regulated at the state, federal and international level. These regulations impose strict requirements on the collection, storage, and use, and disclosures of patient health data, making it difficult for developers to access and utilize large-scale datasets with intact metadata. To identify and mitigate potential biases, developers need to analyze their training and testing data for factors important to the performance of the algorithm as it relates to the device's intended use, such as age, gender, race, ethnicity, and socioeconomic status. However, privacy requirements may limit the collection and use of these demographic variables, making it challenging to conduct comprehensive bias analyses.

- AdvaMed believes strongly that all personally identifiable health data should be subject to robust protections and that comprehensive federal privacy legislation should be implemented in conjunction with regulations, guidance, and resources that take into account the unique context of certain sectors, especially healthcare.

- AdvaMed supports considering whether HIPAA should be amended so that the law would directly apply to all healthcare providers. Alternatively, AdvaMed advocates a HIPAA "opt-in" for non-covered healthcare providers.

- Under a HIPAA opt-in, medtech companies offering AI products and services not directly subject to HIPAA's privacy and security regulations may, nonetheless, choose to voluntarily comply with HIPAA regulations with respect to such products and services to promote operational consistency within the healthcare ecosystem and provide assurances to their HIPAA-covered business partners.

- If a medical AI application is regulated as a medical device, the relevant medical device regulator may have requirements that the medtech companies must meet in terms of information and metadata relating to datasets used to train and validate AI models. Privacy law requirements for de-identification and/or minimization of personal data or metadata can at times be at odds with these requirements. Medtech companies need to be able to: (1) access, store and retain training and validation datasets (and metadata) over a certain period of time to meet medical device requirements; and (2) prove that their dataset is robust and representative of the target patient cohort. In order to conduct a bias analysis, for example, patient health and demographic 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.

- The privacy risks for patients/consumers must be balanced against the need for robust data sources needed to train AI models. Novel regulatory frameworks are needed to ensure this balance is struck adequately since more data will allow the creation of better, more accurate, and less biased AI models. New frameworks for health data regulation and protection should consider the outdated limitations presented by HIPAA, for example, and contemplate that data not considered "health"-related could be used to train AI models that may be applied in a healthcare setting. We also recommend clear guidelines around patient consent for data used to develop AI that balance patient privacy and allow for innovation in AI.

3. *What are the various applications of AI in clinical or operational contexts?*

AI has numerous applications in both clinical and operational contexts. In clinical contexts, AI-enabled devices assist in data acquisition, quantification and objective assessment, decision support, and predictive analytics. Examples include improving the accuracy and consistency of medical imaging, reducing the risk of adverse reactions, providing quantitative measurements and objective assessments, analyzing patient data to support diagnosis and treatment decisions, and predicting future outcomes.

In operational contexts, AI is utilized to improve efficiency by streamlining workflows, optimizing resource allocation, scheduling, and inventory management. Examples include automating tasks such as report generation and data management, identifying bottlenecks, and optimizing resource utilization to manage the workload of healthcare professionals.

Approximately 700 AI-enabled medical devices have been evaluated and given marketing authorization by the FDA (footnote 1 includes a list of these FDA-authorized devices). The following list of clinical functions represents a small sample of the functionality currently provided by FDA-authorized AI medical devices:

- Aid in cancer screening by identifying and quantifying suspected abnormalities, improving diagnostic accuracy, and reducing recalls,
- Triage stroke or pneumothorax patients to ensure time-sensitive access to appropriate therapies,
- Identify bone fractures that may not be obvious to human readers,
- Effectively and efficiently detect coronary artery disease, reducing unnecessary care and enabling the most appropriate treatment options,
- Enhance the automated aspects of ultrasound to better evaluate shock, specifically including helping differentiate the cause of the patient's shock,
- Detect and interpret retinopathy in diabetic patients and recommend referral to an ophthalmologist as appropriate,
- Using a series of PET images (or other data) to investigate lesion response post-treatment in cancer cases,

- Using AI to analyze CT or MRI images to help perform radiation therapy planning, and
- Assist in patient positioning for medical imaging devices such as MRIs.

4. How does AI distinguish itself from other healthcare technologies? How does AI support existing healthcare technologies?

AI distinguishes itself from other healthcare technologies by its ability to analyze vast datasets to assist physicians, supplement and enhance the clinical process, and offer personalized healthcare solutions. AI is capable of analyzing large datasets, uncovering patterns and insights that may be missed by conventional healthcare instruments or techniques, and rapidly processing data to produce data-driven findings and recommendations that can be used to inform clinicians' and patients' care decisions.

AI supports existing healthcare technologies by optimizing administrative operations, bolstering the efficiency of imaging, facilitating remote patient monitoring, improving patient information systems, and assisting healthcare providers in making informed clinical decisions. AI integrates with and builds upon existing technologies, such as electronic health records, medical imaging technologies, and healthcare devices, to provide healthcare professionals with more comprehensive, precise, and actionable information.

5. What measures can be employed to guarantee proper reimbursement and coverage for AI technologies in healthcare?

We are witnessing one of the greatest advances in human history, with rapid, widespread adoption of AI across industries. The healthcare sector—and the millions of patients we serve—are at risk of falling behind due to myriad factors, chief amongst them being misalignment of incentives and lack of intentional funding to maximize adoption. Appropriate payment for adoption and use of AI technologies will be critical to ensuring patient access to and benefit from these innovations. Our recommendations in this response are informed by successful federal and state initiatives from the past decade which have transformed care in our nation and empowered patients.

Healthcare provider investment in transformative AI technologies must be supported by reimbursement policies, otherwise these technologies will languish. To ensure AI technologies' adoption and use in healthcare, these technologies must be approved for coverage in programs such as Medicare and private insurance plans. As the nation's largest payer of healthcare, Medicare's policies on coverage and payment for AI become especially critical, because private payers and state Medicaid plans often look to Medicare as they establish their own coverage policies.

There will be no "one size fits all" reimbursement policy for every AI technology. Instead, appropriate payment mechanisms will 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 will be critical to ensuring appropriate reimbursement. Below, we discuss specific recommendations and considerations regarding AI coverage and payment policy needs.

Medicare Benefit Category Limitations

We believe Medicare has regulatory authority to provide access to AI technologies within its existing benefit category structure. However, its regulatory framework currently lacks the specificity and clarity to provide coverage and payment for digital technologies broadly and for AI and software specifically, because its regulations did not anticipate the advent of digital health technologies used for beneficiary care. The result has been incremental, technology-specific changes, with many AI and software innovators struggling to find pathways to coverage and payment for their innovative technologies. While we appreciate CMS' efforts to provide national pricing for certain AI technologies, we believe access to a higher standard of care for Medicare beneficiaries will be jeopardized unless CMS takes a much broader approach to developing a framework across the program's benefit categories for differentiating types of AI/ML technologies, understanding their value in the context of specific healthcare services, and how values should be translated into specific payments. These consequences may be especially serious for medically underserved communities in both rural and urban areas and, as such, contribute to exacerbating existing disparities in healthcare outcomes for certain racial and ethnic groups. A more comprehensive and systematic solution is needed across and within Medicare's benefit categories to address coverage issues if beneficiaries are to benefit from AI's promise of personalized treatments, improved diagnostics and screening, and more accurate procedures. We therefore recommend Congress urge CMS to evaluate methods for aligning Medicare's Benefit Categories, and any additions to these categories, along currently accepted categories of AI/ML technologies.

Impact of Budget Neutrality Requirements

Generally speaking, Medicare's various payment systems are required to maintain budget neutrality while developing new payment and coverage policy. For example, the Omnibus Budget Reconciliation Act of 1989 requires that Medicare preserve budget neutrality when adjusting physician payment rates, and that any estimated increase of $20 million or more to the Medicare Physician Fee Schedule in a given year must be offset by cuts elsewhere. This requirement 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/ML technologies, because the funds for these expansions come at the cost of other services under the same payment system. We therefore urge Congress to consider legislative solutions to address the impact of budget neutrality constraints on coverage and adoption of AI technologies.

Algorithm-Based Healthcare Services

A subset of AI/ML technologies we are calling algorithm-based healthcare services (ABHS), which include Software as a Service (SaaS) procedures, are rapidly developing and becoming increasingly important to deliver optimal patient care. ABHS are clinical analytical services delivered by FDA-authorized devices to a healthcare practitioner that use artificial intelligence, machine learning, or other similarly designed software to produce clinical outputs for the diagnosis or treatment of a patient's condition. ABHS provide quantitative and qualitative analyses, including new, additional

clinical outputs that detect, analyze, or interpret data to improve screening, detection, diagnosis, and treatment of disease.

However, adoption of and subsequent beneficiary access to ABHS are conditioned on whether there are appropriate Medicare payment pathways that provide stability and certainty for providers adopting ABHS. In the Calendar Year (CY) 2023 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS established a policy for the separate payment of SaaS add-on codes, excluding SaaS from the packaged payment policy at 42 CFR 419.2(b)(18). As CMS recognized in the CY 2023 HOPPS final rule, the number of such services going through the FDA review process has and will continue to rapidly increase. As such, we believe CMS should establish a dedicated section of the HOPPS rule to ABHS, as opposed to limiting discussion and consideration of these services within the New Technology APC section of the preamble text. Further, we believe CMS should provide much needed stability and certainty regarding SaaS by formalizing the exception to the packaged payment policy in regulatory text. We offer the following recommended revision at 42 CFR 419.2:

419.2 Basis of payment.

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   (b) *Determination of outpatient prospective payment rates: Packaged costs.*

* * *

         (18) Certain services described by add-on codes except as provided in § 419.2(d).

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   (d) *Determination of hospital outpatient prospective payment rates: Separately paid costs.* Algorithm-based healthcare services, including Software as a Service procedures, assigned to CPT (Current Procedural Terminology) add-on codes will be paid separately at an amount equal to the amount of the payment for the add-on procedure when the service is furnished without the standalone CPT code. These codes will be assigned to identical ambulatory payment classifications and status indicator assignments as their standalone codes. Separate payment will be made available for these services if the following criteria are met:

         (1) The device delivering the service has been approved or cleared by the FDA;

         (2) The service has received a CPT code; and

         (3) The service is billed concurrent with the associated service code.

Beyond the current SaaS pathway, we believe that additional changes are needed to ensure appropriate payment systems are in place for ABHS. We, therefore, offer the following three recommendations.

First, we believe CMS should revise the New Technology APC application process for ABHS. The application process should be tailored to the unique characteristics of ABHS, while staying true to the policy priorities CMS established as part of the current New Technology APC application requirements (including the creation of procedural C-codes as needed). Further, the American

Medical Association's (AMA) Current Procedural Terminology (CPT) Editorial Panel recently revised its code application questions to include specific items for software and algorithms, and this provides a parallel example of how CMS could update the New Technology APC process for ABHS.

As an example, eligibility for The New Technology APC should be specifically tailored for ABHS, including the following eligibility criteria: (1) ABHS that impact care delivery enough to warrant having a unique code under the Healthcare Common Procedure Coding System (HCPCS), (2) a new ABHS service or procedure that influences clinical decision making, improves the quality of care delivered, and does not reflect all of the resources required to provide the service, or (3) a new ABHS service that provides a separate and distinct output produced either during or subsequent to the underlying procedure that detects clinically relevant data, analyzes and/or quantifies data to produce a separate and distinct output, or interprets data and independently generates a separate and distinct output.

Second, we believe CMS should modify the current New Technology APC policies as they relate to ABHS both currently assigned to a New Technology APC and for future ABHS (including via a potential New Technology APC for ABHS application pathway). Specifically, we recommend CMS: (1) provide stability for ABHS developers by assigning ABHS to a New Technology APC for at least five years; and (2) waive the Universal Low Volume APC policy for ABHS assigned to a New Technology APC. Both recommendations are intended to ensure stability during the New Technology APC period. As it relates to the five-year price stability period, we note that this aligns with the lifespan of a Category III code and is necessary to ensure appropriate data collection and analysis can occur while hospitals adopt ABHS. Further, the five-year stability is intended to ensure there are not variations in New Technology APC assignment based on misreported or omitted cost information. In recent years, including the CY 2024 HOPPS final rule, we have seen how the existing policies create payment aberrations that pose serious threats to the adoption of ABHS such as confusion among adopters and a chilling effect on innovation.

We appreciate that in the CY 2024 HOPPS final rule CMS reversed course on the proposed use of the Universal Low Volume APC policy for Liver Multiscan Service (APC 1511). CMS agreeing to wait for more claims data is the correct approach given it is well-known and understood that innovative technologies like ABHS require stability and certainty to ensure continued development and beneficiary access. However, we do not believe it would be appropriate for CMS to, on an annual basis, undertake rulemaking to modify New Technology APC placement for ABHS, including the need to utilize equitable adjustment authority to prevent the Universal Low Volume APC policy from going into effect. We believe it is in the best interest of Medicare beneficiaries and their providers to have stable access to and consistent payment for innovative technology like ABHS. Permanently waiving the Universal Low Volume APC policy for ABHS is an appropriate, immediate action CMS should take in the upcoming rulemaking cycle.

Third, we believe CMS must be proactive in considering APC assignments for ABHS. While some ABHS can be appropriately assigned to an existing clinical APC, CMS should begin to consider policy options for future ABHS that may not meet the criteria for assignment to current clinical APCs. In recognition of the continual evolution of ABHS, we believe CMS should continue to work with developers to ensure ABHS can be appropriately transitioned out of New Technology APC payments after five years and be assigned to an appropriate clinical APC.

Coverage and Payment for AI Technologies under the Physician Fee Schedule

For the past several years, CMS has contemplated revisions to the Practice Expense (PE) methodology of the Physician Fee Schedule (PFS). The PE methodology is intended to account for the costs of supporting a physician's practice, through both direct (such as clinical labor, supplies, and equipment) and indirect practice expenses (such a clerical payroll, office expenses). We are concerned that specific assumptions in the methodology—specifically, that AI should typically be considered an indirect practice expense—create major disincentives for physicians to incorporate new technologies into their practices due to the lack of appropriate payment. We also believe this methodology needs to be transparent and allow stakeholders to easily understand the impact of proposed policy changes. We, therefore, recommend urging CMS to publish a freestanding request for information for all stakeholders to provide their recommendations for a comprehensive rethinking of the overall assumptions and payment methodology for AI/ML technologies in all Medicare payment systems, with a separate focus on the methodology CMS uses for measuring practice expenses in the PFS to reflect current and future trends in healthcare delivery. It is urgent CMS start this process immediately if beneficiaries are to benefit from the wide variety of digital advances in healthcare delivery and providers are to be encouraged to incorporate these advances into their practices.

Incentivizing Adoption of AI Technologies

In addition to the above, we believe incentive payments to hospitals and/or physicians could support incorporation of AI technologies into providers' workflows. We have seen the impact of similar investments in innovation through the rollout and adoption of Electronic Health Records (EHRs) under the Promoting Interoperability Program (formerly the EHR Meaningful Use Program). Created by the Health Information Technology for Economic and Clinical Health Act, the Promoting Interoperability Program encourages eligible professionals, hospitals, and critical access hospitals to adopt, implement, upgrade, and demonstrate meaningful use of certified EHR technology. During the early years of the program, successful participants received positive incentive payments based on their successful participation. We believe a similar incentive structure could spur more widespread adoption of AI technologies and, in turn, improve the quality of care and outcomes for Medicare beneficiaries.

Supporting Care Delivery Innovation

This RFI provides an opportunity to provide critical push and support for AI technologies that target telemedicine services. Telehealth adoption peaked at 40% of all office visits in USA during the pandemic but has now plummeted to ~5% despite a majority of Americans wanting and preferring telehealth. The burden of delivering telehealth visits in a traditional clinic are substantial (e.g., consenting patients for phone visits, managing video connectivity issues).

AI technologies have shown to ease the burden of running a hybrid (in-person and telehealth) clinic. These will play a critical role in ensuring beneficiaries' access to timely, high-quality care not only in rural areas, but traditionally disenfranchised urban and semiurban populations. The waivers

authorized by Congress during the COVID-19 Public Health Emergency at the onset of the pandemic drastically changes our understanding and assumptions about the nature of healthcare services delivery and expanded our perspectives on the appropriateness of serving patients in the community and their homes. These waivers applied across provisions of Medicare and Medicaid statutes, regulations, and other national and local coverage and payment policies, expanding access to telehealth and other communication technology-based services, such as remote patient monitoring and diagnostic testing. We remain concerned a return to the constraints of the statute and underlying CMS regulatory policies will unduly impact underserved populations and pose significant constraints on Medicare beneficiaries' ability to access high-quality care in a timely manner. We therefore urge Congress to not only extend audio-only and audiovisual telehealth services for Medicare beneficiaries, but directly support AI technologies that are solving the aforementioned care delivery problems.

Efficacy, Accuracy, and Transparency

6. ***What clinical evidence exists regarding the efficacy and accuracy of AI-driven healthcare solutions?***

AI-enabled medical devices with FDA marketing authorization have substantial premarket and post-market data demonstrating device safety and efficacy. Manufacturers are responsible for performing the appropriate testing (non-clinical and/or clinical) to evaluate the safety and effectiveness of their device for its specified intended use and intended population. FDA's premarket review includes an assessment of the adequacy of the submitted performance and safety evaluations. During premarket review, FDA can ask for additional testing to ensure the device meets the appropriate thresholds for safety and performance for the respective device type. Medical device manufacturers (MDMs) also have ongoing post-market requirements and responsibilities to monitor the performance and safety of their regulated medical devices, including implementing robust quality management systems, conducting post-market surveillance studies, actively monitoring user feedback, and reporting serious adverse events to FDA. The routine monitoring and evaluation of the clinical data from real-world use of the device is leveraged by MDMs for continuous improvement of their AI algorithms; refining their AI models as new clinical data becomes available and real-world evidence is collected.

There is a growing body of evidence supporting the efficacy and accuracy of AI-driven healthcare solutions. We offer some examples;

- AI in Clinical Virology: A comprehensive review in the field of clinical virology has shown that AI, machine learning, and deep learning have significantly enhanced diagnostic precision, therapeutic interventions, and epidemiological monitoring.[3]
- AI-Produced Certainties in Healthcare: AI has been found to enhance precision, personalization, and overall improvement in medicine.[4]

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[3] Padhi, A., Agarwal, A., Saxena, S.K. *et al.* Transforming clinical virology with AI, machine learning and deep learning: a comprehensive review and outlook. *VirusDis.* **34**, 345–355 (2023). https://link.springer.com/article/10.1007/s13337-023-00841-y

[4] Tretter, M., Ott, T. & Dabrock, P. AI-produced certainties in health care: current and future challenges. *AI Ethics* (2023). https://link.springer.com/article/10.1007/s43681-023-00374-6

7. *What best practices are recommended to ensure sufficient availability and use of health data for AI-driven healthcare solutions?*

Unlocking the potential of AI-driven healthcare solutions is linked to the availability and quality of the data used to build and evaluate these technologies. Ensuring the availability and ethical use of health data requires a multifaceted approach. We offer the following considerations and recommendations to promote the availability of quality health data necessary to develop trustworthy AI algorithms:

- Establishing international consensus standards and globally harmonized frameworks that promote consistent expectations for algorithm development and data quality. Timely recognition of these standards by FDA.

- FDA development of guidance related to best practices in the development of different types of AI (e.g., continuous learning algorithms, adaptive models) and premarket review practices for these technologies (e.g., mitigating unwanted bias, standardizing terminology).

- Standardization of data collection, cleansing, and storage methods.

- Foster collaboration among healthcare technology companies, healthcare providers, and researchers to enable the sharing of healthcare data for AI development by modernizing HIPAA de-identification standards to allow for the sharing of 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) in their current state cannot reasonably enable the high-volume data usage and sharing required to develop safe and accurate AI models with effective mitigations against unwarranted bias.

- De-identification and anonymization techniques that protect individuals' privacy rights while allowing developers access to datasets with necessary data elements (e.g., race, ethnicity, gender, age, etc.) are needed to enable robust AI algorithm development.

- Promoting best practices for good data quality at the point of entry by care providers and providing clarity on secondary usage rules for health data retroactively.

- Flexibility to pursue different approaches to obtaining and utilizing data is crucial to ensuring innovation is not limited by data access. For example, synthetic data techniques can be used to augment datasets when high-quality clinical data is lacking.

- Create a centralized system, perhaps at a state or federal level, for aggregating data like health information exchanges but for research and development purposes. Create adequate, but not overly onerous, processes for researchers to access these data sets. There are many different data aggregators and third-party data vendors whose data is not standardized. Additionally, there are a handful of vendors that provide services needed to link data together (e.g., tokenization and expert determination). Together, the data vendors and third-party linking services are the current gatekeepers to available data. These parties' involvement in the data selling, licensing, and exchanging process adds unnecessary layers and commercial interests to data access and use for

healthcare research. They also typically charge significant sums of money to access and use this data with no direct benefit to patients, which raises ethical questions about the commodification of patient data.

8. *What guardrails or accountability mechanisms could be set to ensure end-to-end transparency?*

While the public discussion of AI and Machine Learning (ML) has increased in recent years, the FDA has been reviewing and authorizing AI/ML enabled devices for over 25 years, and we believe the existing regulatory framework provides sufficient guardrails to ensure end-to-end transparency.

FDA's existing labeling framework for medical devices provides an effective mechanism for manufacturers to communicate the essential information needed for the safe and effective use of the device by requiring certain information such as the device's intended use, clear and detailed instructions for use, warnings and limitations, and performance summaries. Transparency in device labeling can be enhanced by expanding FDA's authorization to permit use of electronic labeling (e-labeling) in lieu of paper labeling. E-labeling, particularly for software-based devices, is a more efficient and environmentally conscientious method to transfer information to the user. Further, e-labeling offers flexibilities in the presentation of information that can promote healthcare equity. For example, e-labeling font size can be adjusted for the visually impaired and can be provided in multiple languages and formats.

Under the existing regulatory framework, MDMs are also required to implement robust quality systems and adverse event reporting mechanisms to ensure ongoing transparency and accountability. Quality systems ensure that AI-driven solutions are designed, developed, and manufactured in accordance with established standards and regulations.[5] Adverse event reporting is also a critical component of transparency and accountability. MDMs are required to have systems in place to monitor and report serious adverse events and incidents to the FDA.[6] FDA, in turn, monitors and analyzes adverse event reports and has regulatory authority to take action, when appropriate.

Medical device lifecycle data, which is available on FDA's public database,[7] is another means to promote transparency. The searchable public database includes the premarket summaries of FDA authorized devices, adverse event reports, and device recalls information. Collectively, these existing regulatory requirements, responsibilities, and resources ensure transparency for all stakeholders and promote public trust.

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[5] https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-current-good-manufacturing-practices-cgmp
[6] https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems#requirements
[7] https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTPLC/tplc.cfm

9. *How can we ensure guardrails are put in place to mitigate risks such as disparate impact from racial, ethnic, and other biases?*

When considering bias in AI/ML-enabled medical devices, it is important to distinguish between unintended bias and bias for targeted specialization. In the case of targeted specialization, bias may be beneficial to the intended patient population (e.g., if it is demonstrated with valid scientific evidence that symptoms are expressed differently in a certain sub-population, the AI tools may be optimized for that population with bias). Conversely, unintended or unwarranted bias can lead to negative consequences, such as causing unwanted differential performance across patient subgroups. The discussion below refers to mitigation of negative impact bias.

For regulated medical devices, there are already guardrails and frameworks in place that assess and mitigate risks of negative impact bias. In 2021, FDA, United Kingdom's Medicines and Health products Regulatory Agency (MHRA), and Health Canada jointly issued the "Good Machine Learning Practice for Medical Device Development: Guiding Principles" document.[8] This document lays the foundation for a globally harmonized approach of best practices for the development of safe, effective, and high-quality medical devices that use AI/ML. FDA's review of premarket submissions assesses the device's safety and effectiveness for the intended patient population(s), which, in the case of AI/ML-enabled devices, includes an assessment to ensure negative bias has been adequately mitigated for the respective patient population. Last year, AdvaMed recommended FDA issue guidance on best practices and considerations for addressing unwanted bias.[9] In response, FDA has indicated that it intends to issue a draft guidance in 2024 to address AI/ML lifecycle management and premarket submission recommendations.[10] The guidance is expected to enhance clarity and consistency of FDA review practices and criteria for assessing the adequate mitigation of unwanted bias. In the interim, the medical device industry continues to adhere to risk management practices outlined in FDA-recognized consensus standards.[11] Additionally, the device industry recognizes certain commonly understood methods to mitigate unwanted bias such as increased data diversity that reflects the intended user population (e.g., age, sex, race), utilization of data from different sources, ensuring the size of the data sets is adequate to promote generalizable performance for the intended patient population, and reduction of overfitting (force-fitting) models to the training data. Challenges can arise when access to large and diverse data sets is limited or restricted.

While transparency and disclosure about the AI/ML system should, generally, not be considered a primary method to mitigate bias, this may help decrease the risks attributed to error or misuse error by ensuring that the user is able to interpret the output more effectively for the specific patient or

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[8] https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles
[9] https://www.regulations.gov/comment/FDA-2022-D-2628-0014
[10] https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2024fy2024
[11] The device industry leverages standards such as Medical Devices- Application of Risk Management to Medical Devices, ISO 14971: 2019

population. The information provided in device labeling should be tailored to allow the user to make informed decisions regarding their use of, and interaction with, the AI system.

10. What are accountability mechanisms that can be put in place to ensure that there is an accurate spread of information?

As discussed above, FDA's existing framework, including labeling requirements and adverse event reporting, are mechanisms that are intended to provide accountability. The labeling framework provides an effective mechanism for manufacturers to communicate the essential information needed for the safe and effective use of AI-enabled technologies. The labeling framework can be enhanced by expanding FDA's authorization of e-labeling which will ensure that product information is provided in a clear and timely manner and shared in a way that best supports patients and healthcare professionals in understanding the benefits, risks, and limitations to safe and effective use of the product.

In addition, adverse event reporting is a critical component of transparency and accountability. Medical device manufacturers must have systems in place to monitor and report adverse events, incidents, or malfunctions associated with their device. This includes collecting and analyzing user feedback, conducting post-market surveillance studies, and promptly investigating and addressing any issues that arise. Adverse event reports are shared with regulatory authorities, healthcare providers, and the public, as appropriate, to ensure timely and transparent communication about potential risks and corrective actions.

To ensure accurate spread of information, the FDA should remain the sole entity overseeing and enforcing the regulatory framework and accountability mechanisms for regulated medical devices.

11. Are there specific examples of AI applications that have significantly improved patient outcomes or streamlined healthcare processes?

Among regulated medical devices, the use of AI is most utilized in the field of medical imaging. For example, 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 ECG diagnostic software enables faster diagnostics of heart disease. Another notable example is in the use of AI tools for the prediction of sepsis in adults[12], which is a leading cause of morbidity and mortality around the world.

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[12] "Artificial Intelligence for the Prediction of Sepsis in Adults." Canadian Journal of Health Technologies, March 2022, Vol. 2, Issue 3 https://www.ncbi.nlm.nih.gov/books/NBK596676/pdf/Bookshelf_NBK596676.pdf

Ethical & Regulatory Considerations:

12. With the increasing reliance on AI in healthcare decision-making, what ethical and regulatory considerations need to be addressed to ensure patient safety, privacy, and equity?

Premarket and post-market regulatory oversight of medical devices, including AI/ML-enabled devices, is and has been, enforced by FDA for decades. As discussed above, the FDA's premarket review of AI-enabled devices includes an assessment of the rigorous testing, validation, and risk mitigation conducted by device manufacturers. FDA's regulatory oversight continues in the post-market part of the device's lifecycle with ongoing monitoring of AI-based technologies to mitigate risks and ensure compliance with established standards and regulations.

On December 29, 2022, Congress granted FDA the authority to review and authorize pre-specified change(s) to a device in a premarket submission without necessitating the device manufacturer obtain a new marketing authorization known as the Predetermined Change Control Plan (PCCP). We applaud FDA and Congress for this innovative concept that enables software updates to be made efficiently and more rapidly to help improve patient health while still ensuring the safety and effectiveness of the device. The authority applies to all medical devices, but, if implemented in accordance with the statutory authority, has great applicability to AI/ML-enabled devices in particular, because it will enable the regulatory framework to keep better pace with the rapid-change nature inherent to AI/ML technologies. In April 2023, FDA issued a draft guidance titled, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/ Machine Learning (AI/ML)- Enabled Device Software Functions.[13]" As noted in AdvaMed's comments to the docket for this draft guidance,[14] the recommendations in the guidance place limits on the use of PCCP that are inconsistent with the statutory authority and greatly reduce the practical utility of the program. For example, the draft guidance states, "… FDA expects that modifications included in a PCCP should also maintain the device within the device's indications for use." The prohibition of modifications to the indications for use within a PCCP is inconsistent with the statutory authority.[15] We encourage FDA to issue guidance on the use of PCCP that is consistent with the broad statutory authority and ensure it is implemented consistently across the review teams. In addition, the PCCP data and documentation recommendations in the draft guidance are overly prescriptive and impractical for many common types of changes to AI algorithms. We encourage FDA to ensure that they appropriately balance the need for premarket confidence with postmarket efficiency to ensure that PCCPs can be utilized appropriately for postmarket modifications to further AI innovation.

The benefits and promise of AI in healthcare can only be achieved when there is equitable access to these devices.

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[13] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial

[14] https://www.regulations.gov/comment/FDA-2022-D-2628-0014

[15] Per 21 U.S. Code § 360e–4, any device modification(s) may be authorized in a PCCP so long as the device remains safe and effective, and for cleared devices the device would remain substantially equivalent to the predicate.

Ensuring Privacy

- Data privacy and security must be prioritized to protect patient's sensitive health information. Informed consent and patient autonomy are essential for involving patients in AI-driven healthcare decisions.

- The healthcare sector has experienced significant advancements in medical diagnoses, assessments, and treatment discoveries with the use of AI. Along with these potential benefits, it is important to consider the data protection requirements for large-scale processing of health data required to power AI models as well as the additional re-identification risks from the use of AI techniques/processes. Healthcare companies must maintain a data privacy compliance infrastructure that can scale through the use of privacy-enhancing technologies and automation to keep up with rapidly evolving AI technology and regulatory landscape to ensure safe and accurate AI models and tools are free from unwarranted biases or errors.

- When patients understand what data is shared about them and are informed about how that data will be used, issues related to privacy are allayed. Greater transparency in the recording, sharing, and analysis of data would help in striking an informed balance between greater data aggregation for AI model training and risks to patient privacy[16].

- Equity of data used for AI in healthcare is determined by who is willing to participate in healthcare. Certain groups of individuals may be more or less likely to seek care and, thus, are more or less likely to have their data recorded and potentially used to address equity issues in healthcare. Until the broader historical, systematic, and structural equity issues in the delivery of healthcare are addressed, the underlying representativeness of data used in AI models will always be suboptimal. Statistical techniques to address equity for underrepresented populations may be used but these techniques themselves may be fraught with bias.

- In commercial settings, when data is not labeled as being used for research purposes, there is a patchwork of state and privacy laws that make it difficult for companies to govern how the data is used and for patients and consumers to understand how their data is used. Only when data is marked as "*intended for use*" in research do regulations about patient privacy and the ethical conduct of research apply. Bad commercial actors may simply never conduct "research" but instead engage in "market analysis", "user profiling", "product development", or other proprietary activities that are arguably the same as the conduct of research and produce the same outputs of a research study but are not called research. We need regulatory frameworks around the use of health data for AI models that are user-friendly and ensure the privacy of personal health data.

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[16] Jain S, Krumholz HM. Patient Privacy and Data Provenance in Pulmonary and Critical Care Research Using Big Data. Annals of the American Thoracic Society (Online). 2024;21(4):538-540. doi: https://doi.org/10.1513/annalsats.202305-497ip

13. How can the use of AI in healthcare provide benefits while safeguarding patient privacy in clinical settings?

Examples of potential AI benefits for surgeons include:

- Real-time surgical scene analysis and decision support;

- Real-time anatomy recognition and identification;

- Real-time surgical phase recognition and peer approach assessment (e.g., at this stage of the procedure, 80% of surgeons do XYZ next);

- Post-operative video assessment of techniques and training insights/recommendations for new surgeons; and

- Pre-operative planning, identifying similar cases, enabling surgeons to review what others did to ensure cases went well and in what situations cases had challenges in order to avoid similar complications.

Approaches for safeguarding patient privacy in the situations above include:

- Leveraging industry standard best practices around medical data storage and transfer security (pseudo-anonymization, tokenization, encryption, etc.)

- Developing and deploying with privacy-preserving techniques (some of which may also utilize AI to enhance privacy). For example:

    o AI-generated synthetic datasets used to train healthcare AI models do not constitute personal data under data privacy laws when implemented properly;

    o Federated learning (AI models trained across multiple decentralized devices holding local data samples without exchanging them so that sensitive data does not leave the device);

    o Differential privacy;

    o Secure data sharing using blockchain and other secure platforms;

    o Homomorphic encryption; and

    o AI software that detects and redacts personal information or identifying elements in images to preserve privacy.

14. What regulations, policies, frameworks, and standards should entities utilizing AI adhere to, and what mechanisms are in place or should be in place to supervise and enforce them?

As discussed above, FDA has a robust regulatory framework to oversee all medical devices, including AI/ML devices. Their oversight is guided by a framework that includes a rigorous pre-

market review process that assesses medical device performance, reliability, and safety, as well as extensive monitoring and surveillance requirements after devices are authorized for sale. These ensure continued safety and effectiveness throughout the device lifecycle.

We commend Congress for the enactment of the PCCP authority. This streamlined approach to enhance premarket efficiency for modifications to devices, including AI models, is a promising example of how new and right-sized policy development can occur in response to changes in technology or regulatory needs. We advocate for continued robust stakeholder engagement regarding AI policy considerations, including implementation of PCCPs. Together, we can help identify and develop additional novel regulatory approaches, as needed, to enable the unique features and advantages of AI.

Entities that utilize AI-enabled devices should follow existing best practices and standards for regulated medical devices, including compliance with data protection laws (e.g., HIPAA) and ethical deployment and use of the devices.

Global healthcare companies are required to comply with both general AI regulations (such as the EU AI Act and various U.S. state AI regulations), sector-specific AI regulations (FDA-recognized AAMI 34971 Standards) and global privacy laws, as well as considering non-binding frameworks and principles, such as the IMDRF's of Good Machine Learning Practice to promote the development of safe and effective artificial intelligence/machine learning-enabled (AI/ML) medical devices. Fulsome and constantly improving compliance, privacy, information security, and quality programs that take into account all applicable regulations, policies, frameworks, and standards are essential for any healthcare company that utilizes AI. The rapid development of AI technology, the sensitive nature of health data, and the enhanced risks of AI in the healthcare space require such large investments in compliance infrastructure and expertise.

Current laws, policies, and regulations do not adequately address privacy and ethical risks and allow for the best use of patient health data. Assembling an optimal framework for the regulation and oversight of data used in AI models for healthcare needs true innovation, boldness, and originality. Using current regulatory schemes that were not designed to keep pace with the velocity of advancements in health data collection, processing, and analysis will result in a piecemeal approach and will not achieve the best outcomes for patients. Current laws and regulations were contemplated and enacted at a very different time and for a very different healthcare landscape. Further, all such laws and regulations that govern the collection and use of health data must be harmonized to enable cutting-edge healthcare research and improved patient health outcomes.

Other Considerations:

15. *What emerging trends do you foresee in the intersection of AI and healthcare?*

Foreseeable emerging trends in the intersection of AI and healthcare include:

- Personalized healthcare driven by AI algorithms that analyze vast amounts of patient data to tailor recommendations based on individual characteristics and needs.

- Integration of AI with other emerging technologies such as wearable devices, genomics, and telehealth to enhance the delivery of personalized healthcare, enabling proactive health monitoring, early disease detection, and remote patient management.

- Continued development and improvement of Clinical Decision Support software that leverages new data and knowledge gained by greater adoption and utilization of these tools.

- Shifts from AI technologies developed from siloed, disparate data streams (unimodality) towards those developed from multi-modal data (imaging, waveform, genomics, etc.) to provide a more comprehensive view of patients' health data.

- AI-augmented tools for more robust medical product development (e.g., drug and device development)

16. Are there any promising innovations or potential disruptions on the horizon that warrant attention from policymakers?

Promising innovations and potential disruptions on the horizon that warrant attention from policymakers include:

- Advancements in AI-driven personalized medicine, where algorithms analyze vast datasets to tailor treatments to individual patients' lifestyle factors and medical history. This approach has the potential to improve patient care and reduce adverse events by optimizing care plans based on the patient's specific data.

- As use of these tools increases, they will disrupt the current standard of care and improve public health, by decreasing patient morbidity and mortality. Evidence of success in the use of such specialized tools already exists, such as in the use of diagnosing of diabetic retinopathy.[17]

We recommend policymakers continue to proactively engage with medical device innovators and stakeholders as AI technology continues to evolve. The importance of education and training for various stakeholders, as appropriate, should remain at the forefront to promote adoption of novel technologies and responsible usage.

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[17] Padhy SK, Takkar B, Chawla R, Kumar A. Artificial intelligence in diabetic retinopathy: A natural step to the future. Indian J Ophthalmol. 2019 Jul;67(7):1004-1009. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6611318/

17. Are there legislative measures that Congress can take to ensure access to safe, reliable AI healthcare services?

We recognize that the pace of innovation is fast, but we believe the FDA's existing regulatory authorities are robust and flexible to ensure the safe and effective use of AI/ML technology in medical devices. As state and federal legislators seek to ensure AI/ML-enabled technologies in all industries are used safely, FDA should continue to maintain regulatory oversight of medical devices, including the interoperability between devices and non-devices. We would appreciate the opportunity to work with legislators to ensure any future regulatory frameworks related to AI/ML products do not create redundant oversight or regulatory confusion for medical devices.

AdvaMed member companies take seriously the level of trust placed in them by patients and have consistently taken action to self-identify best practices to balance innovation with patient protections.

Measures to further improve access to safe and reliable AI healthcare services include:

- Improved policies for access to data sets necessary to develop effective AI algorithms and promote AI innovation.

- Expanding FDA's authorization to permit use of electronic labeling (e-labeling) in lieu of paper labeling. E-labeling, particularly for software-based devices, is a more efficient and environmentally conscientious method to transfer information to the user. Further, e-labeling offers flexibilities in the presentation of information that can promote healthcare equity. For example, e-labeling font size can be adjusted for the visually impaired and can be provided in multiple languages and formats.

- Revising the current FDA guidance on Clinical Decision Support Software to ensure the recommendations better align with the 21st Century Cures Act (e.g., ensure AI-based CDS that produces a single output, such as a recommendation for a particular treatment option that is consistent with common treatment guidelines, wouldn't de facto be regulated as a medical device).

We note that FDA's regulatory framework is only part of the challenge medical device innovators must address to bring their products to market. To get AI and software technologies deployed for use in healthcare delivery, they must also be approved for coverage in programs such as Medicare and private insurance plans. Medicare has regulatory flexibility to provide access to AI and software technologies within its existing benefit category structure. However, its regulatory framework currently lacks the specificity and clarity to provide coverage and payment for digital technologies broadly and for AI and software specifically, because its regulations did not anticipate the advent of digital health technologies used for patient care. The result has been incremental change, with many AI and software innovators struggling to find pathways to coverage and payment for their innovative technologies. A more comprehensive and systematic solution is needed across and within Medicare's benefit categories to address coverage issues if patients are to benefit from AI's promise of personalized treatments, improved diagnostics and screening, and more accurate procedures. In addition, as the nation's largest

payer of healthcare, Medicare's policies on coverage and payment for AI become especially critical since private payers and state Medicaid plans often look to Medicare as they establish their own coverage policies.

Thank you for the opportunity to submit these comments. Please consider AdvaMed as a resource to you and the AI Taskforce on medtech regulatory, data stewardship, reimbursement, and privacy matters as you consider legislation related to AI and medical devices.

Respectfully Submitted,

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