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February 23, 2025

Via Electronic Mail
Mr. Stephen Posnack
Principal Deputy Assistant Secretary for Technology Policy
U.S. Department of Health and Human Services
Assistant Secretary for Technology Policy/Office of the National Coordination for Health Information Technology (ASTP/ONC)
Mary E. Switzer Building
330 C Street SW
Washington, DC 20201

Re: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care

Dear Mr. Posnack,

AdvaMed, the Advanced Medical Technology Association, appreciates the opportunity to submit comments in response to your December 23, 2025, request for information[1] (RFI) on accelerating the adoption and use of AI as part of clinical care.

AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical technology. AdvaMed's member companies, which range from the largest to the smallest medical product innovators and manufacturers, produce innovations that transform health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed advocates for a legal, regulatory and economic environment that advances global health care by assuring worldwide patient access to the benefits of medical technology. The Association promotes policies that foster the highest ethical standards, timely product approvals, appropriate reimbursement, and access to international markets.

We recognize AI as a transformative tool with the potential to improve health outcomes, enhance the efficiency of patient care, reduce costs, and advance healthcare. Right-sized and clarified regulations can promote the development, deployment, and adoption of innovative and trustworthy AI-enabled solutions. AdvaMed is uniquely well-positioned to provide feedback on

[1] https://www.federalregister.gov/documents/2025/12/23/2025-23641/request-for-information-accelerating-the-adoption-and-use-of-artificial-intelligence-as-part-of

frameworks and policy considerations for AI, as our members have been developing and deploying AI-enabled medical devices supporting patient care for over 25 years.

We appreciate the opportunity to submit our high-level recommendations on regulatory reforms to accelerate the adoption and use of AI as clinical care.

1. What are the biggest barriers to private sector innovation in AI for health care and its adoption and use in clinical care?

A. Regulation of AI-Enabled Medical Devices

The medical device industry has more than three decades of experience developing AI-enabled technologies that advance health care. As of December 2025, FDA has authorized over 1,300 AI-enabled medical devices[2], reflecting the sector's longstanding expertise in innovating AI applications in health care. This experience underscores a core principle: innovation thrives when regulatory oversight is transparent, predictable, and capable of keeping pace with technological advancements. These goals can be achieved by advancing regulatory science through the issuance of FDA guidance and timely recognition of international consensus standards, upholding the FDA's existing risk-based regulatory paradigms while adapting when needed to accommodate novel technologies, and ensuring FDA is properly resourced to accomplish these objectives.

B. Coverage and Payment for AI-Enabled Medical Devices

Leaders of this Administration have been outspoken on their concern for the poor health outcomes in the United States despite the abundant resources at our disposal. AdvaMed and the broader medtech community share this deep concern. We also know medtech is a proven part of the solution. Medtech works. But it only works if patients have access to it and clinicians are empowered to use it. Access is complicated by many factors: inadequate or no health insurance coverage; lack of provider coverage of medtech-enabled procedures; inadequate provider reimbursement for medtech-enabled procedures; limited access to specialists and care due to factors including geography and health care provider shortages; limited understanding of available treatment options; and other out-of-pocket expenses associated with health care, such as high deductibles and copayments.

As you know, the Centers for Medicare and Medicaid Services (CMS) plays a critical role in patient access to health care and medtech. Medicare, as the nation's largest health insurer, shapes the health of its 67 million enrollees. It sets precedent in its coverage policies for Medicaid and private insurers. Unfortunately, outdated Medicare laws and regulations often create unnecessary barriers to patient access to many technological innovations, including artificial intelligence software as a medical device and other items and services, along with digital and at-home care. For the past eight years, CMS has issued requests for comments or requests for information related to the adoption of technology and digital medicine, but has taken little action to provide

[2] https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices

clarity on coverage and/or payment for these transformative technologies and the services performed with them.

Adoption of and subsequent beneficiary access to novel digital health technologies, including AI, is conditioned on whether there are appropriate Medicare payment pathways that provide stability and certainty for providers adopting these technologies. While CMS has explored payment policies in specific cases to recognize the role of software as a service (SaaS), software as a medical device (SaMD), and AI technologies in health care delivery, a lack of clear and consistent coverage and payment policies for these categories of technologies significantly limits access under the Medicare program. Our specific recommendations for revisions to CMS' regulation of AI and digital health technologies are discussed below.

C. Data Privacy

Access to high-quality data is pivotal for AI model innovation, as it is crucial for development and validation. Updating data regulatory frameworks, such as HIPAA, to facilitate ethical and secure data-sharing practices will further enhance the development of sophisticated AI tools.

AI researchers require improved access to healthcare data that is both rich enough to support meaningful scientific development and sufficiently de-identified to protect patient privacy from wrongful disclosure or abuse. Policymakers can support advances in healthcare AI innovation by allowing broader use of healthcare data for research, provided identifiers are removed and other HIPAA rules are met (e.g., HIPAA's security requirements and its limitations on "selling" or marketing without prior written permission).

In parallel, a broad, prospective informed consent framework would enable individuals to contribute their data to a centralized repository for future research, enabling reuse across studies and institutions.

2. What regulatory, payment policy, or programmatic design changes should HHS prioritize to incentivize the effective use of AI in clinical care and why? What HHS regulations, policies, or programs could be revisited to augment your ability to develop or use AI in clinical care? Please provide specific changes and applicable Code of Federal Regulations citations.

A. Regulation of AI-Enabled Medical Devices

Effective clinical use of AI-enabled medical devices depends on the development and availability of safe, effective technologies—a responsibility shared by industry and FDA. Medical device manufacturers have a strong record of advancing health care with innovative, reliable AI-enabled devices, and FDA has a long history of reviewing and authorizing such devices. Once in clinical use, both parties continue to monitor device safety through their respective regulatory requirements and responsibilities. FDA's existing premarket and post-market regulations ensure patients and clinicians have access to trustworthy devices. However, by prioritizing certain programmatic improvements, the availability of AI-enabled devices in clinical use can be accelerated without compromising safety or performance.

The De Novo[3] premarket regulatory pathway outlined in 21 CRF Part 860, Subpart D, was created with the goal of fostering the development of innovative medical devices of low to moderate risk. Since its inception in 1997, FDA has authorized approximately 450 devices through the De Novo paradigm. However, FDA's performance reports[4] indicate that less than 50% of De Novo submissions are granted. This low rate of success is in stark contrast to the other premarket pathways (>80% success rate for 510(k) submissions annually). The De Novo program would benefit from greater transparency and consistency in FDA's evidentiary expectations for De Novo submissions. FDA has the authority to implement adaptive, risk-based paradigms, such as increasing the utilization of real-world evidence and conditional authorization with post-market obligations, that if implemented consistently, could meaningfully increase the success rate of the De Novo program and increase patient access and clinical use of AI-enabled devices without compromising patient safety.

In 2022, Congress passed predetermined change control plan (PCCP) legislation[5]. The PCCP authority enables manufacturers to innovate more efficiently and rapidly while still ensuring the safety and effectiveness of the device. 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. This authority is a promising example of how new and right-sized policy development can occur in response to changes in technology or regulatory needs. FDA's AI PCCP guidance document[6] is a valuable tool to promote consistent understanding and implementation of this new process. However, it is important that FDA's implementation of the PCCP framework continues to evolve as AI technology and its use in medical devices continue to evolve. A restrictive or static approach to implementation of the PCCP authority diminishes its intended efficiency to implement device improvements. We encourage FDA to authorize PCCPs that promote efficient post-market changes for AI-enabled devices. If implemented with the intended flexibility, authorized PCCPs can enable the regulatory frameworks to keep pace with the rapid innovation inherent to AI.

Clear and well-scoped guidance is a valuable tool that helps innovators understand regulatory expectations and supports the development of safe and effective devices. In January 2025, FDA issued draft guidance on lifecycle management and marketing submission recommendations for

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[3] Congress authorized the De Novo classification process in the Food and Drug Administration Modernization Act (FDAMA) of 1997. The De Novo classification process is authorized under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). FDA De Novo regulations are outlined in 21 CFR Part 860, Subpart D

[4] https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa-fees/mdufa-reports

[5] On December 29, 2022, 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") added section 515C "Predetermined Change Control Plans for Devices" to the Federal Food, Drug, and Cosmetic (FD&C) Act. Section 515C of the FD&C Act (21 U.S.C. 360e-4) has provisions regarding predetermined change control plans (PCCPs) for devices.

[6] FDA's guidance titled, "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions" was issued as a final guidance document in August 2025. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence

AI-enabled devices[7]. It important that the recommendations in the final guidance are appropriately scoped to align with FDA's established risk-based and least burdensome regulatory principles. Advanced AI systems, such as deep learning and deep neural network models, present unique validation and lifecycle management considerations that may warrant targeted regulatory attention. By contrast, more traditional or less complex machine learning approaches are generally well addressed under existing FDA frameworks. However, the draft guidance appears to apply a one-size-fits-all approach to all AI-enabled devices. It is important that the final guidance distinguish between these categories to allow FDA to focus oversight where risk and uncertainty are greatest while avoiding unnecessary regulatory burden for established technologies. Additionally, certain elements of the current draft, particularly the blanket recommendations for enhanced post-market oversight and the extensive transparency and documentation requirements would create substantial burden without proportionate clinical benefit. We encourage FDA to continue refining these elements in the final guidance to ensure that recommendations therein remain clinically meaningful and consistent with the least burdensome provisions of the Federal Food, Drug, and Cosmetic Act.

Early and frequent dialogue between innovators and FDA reviewers helps enhance mutual understanding and can facilitate the development of innovative devices. Direct one-on-one engagement between FDA and innovators throughout the device development phase, such as through FDA's Breakthrough Devices Program[8], can reduce regulatory surprises and accelerate the path to market for medical devices. A stable and appropriately-resourced FDA that attracts and retains top talent ensures the FDA workforce has the right knowledge base to keep pace with the rate of innovation and promotes consistency during the regulatory review phase. Continued support and reauthorization of user fee agreements like MDUFA[9] are vital because they ensure accountability and resource availability for both the FDA and industry.

B. Securing Coverage and Payment for AI Under CMS' Payment Systems

As noted above, a lack of clear and consistent coverage and payment policies for AI and digital health technologies significantly limits beneficiary access to novel and innovative technologies under the Medicare program. Below are our recommendations for specific changes to CMS' regulations to expand access to AI and related technologies.

1. Hospital Outpatient Prospective Payment System (OPPS)

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[7] FDA draft guidance; "Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing

[8] The Breakthrough Devices Program is implemented under section 515B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e-3), as created by section 3051 of the 21st Century Cures Act (Cures Act), amended by section 901 of the FDA Reauthorization Act of 2017, and amended by Section 3001 of the SUPPORT for Patients and Communities Act (the SUPPORT Act) (the "Breakthrough Devices Program"). The Breakthrough Devices Program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

[9] Medical Device User Fee Amendments (MDUFA); https://www.fda.gov/industry/fda-user-fee-programs/fda-user-fees-explained

a. *New Technology Ambulatory Payment Classification (APC) Improvements*

In the CY 2023 OPPS/ASC 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). We are greatly encouraged by CMS acknowledging the uniqueness of these technologies, and recognizing the need for separate payment and consideration of these services. As CMS recognized in the CY 2023 OPPS/ASC final rule, the number of such services going through the FDA review process has and will continue to rapidly increase. We encourage CMS to provide much needed stability and certainty regarding SaaS by formalizing the exception to the packaged payment policy in regulatory text. We further recommend CMS establish a dedicated section of the OPPS rule to SaMD and related technologies moving forward, as opposed to limiting discussion and consideration of these services within the New Technology APC section of the preamble text.

Beyond the current SaaS pathway, we believe additional changes are needed to ensure appropriate payment systems are in place for novel SaMD, including algorithm-based healthcare services (ABHS)[10]. We therefore offer the following three recommendations.

First, we ask the agency to revise the New Technology Ambulatory Payment Classification (APC) application process for these FDA-regulated, software-based interventions. The application process and criteria should be tailored to the unique characteristics of these technologies, 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). As an example, the application should reflect the impact of a SaMD on care pathways and how these services assist practitioners in the delivery of care.

Second, we encourage CMS to modify the current New Technology APC policies as they relate to SaMD both currently assigned to a New Technology APC and for future technologies (including via a potential New Technology APC for SaMD application pathway). Specifically, we recommend CMS: (1) provide stability for SaMD developers by assigning these technologies to a New Technology APC for at least five years; and (2) waive the Universal Low Volume APC policy for these technologies when 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 this would align with the lifespan of a Category III code and is necessary to ensure appropriate data collection and analysis can occur while hospitals adopt novel SaMD. Further, this five-years of assigned payment 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 OPPS/ASC final rule, we have seen how the existing policies create payment aberrations that pose serious threats to the adoption of these novel SaMD, such as confusion among adopters and a chilling effect on innovation.

[10] ABHS are clinical analytical services delivered by FDA-cleared 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.

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

b. *Transitional Pass-Through Payment (TPT) Improvements*

Under TPT and the new technology APC policies for eligible new devices, CMS provides higher payments to aid with the uptake by hospitals of eligible new medical devices. The current TPT criteria specifically require a device must —

- Be an integral part of the service furnished;
- Be used for one patient only;
- Come in contact with human tissue; and
- Be surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion.

Furthermore, the device cannot be any of the following:

- Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets; or
- A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than radiological site marker).

As AI and SaMD are increasingly introduced for more and more procedures and frequently include components that do not come into contact with patients or represent a capital expenditure, these criteria are inappropriately exclusionary for these technologies. In particular, because capital costs are included in establishing the APC payment rate, the same rationale applies equally when calculating the operating costs for pass-through payments. We therefore urge CMS to consider improvements to the TPT program allowing SaMD and other technologies that do not come into contact with patients, but enable clinicians to provide optimal care to be eligible for additional payments under this program.

2. Physician Fee Schedule

We encourage CMS to consider holistic updates to its fee-for-service payment systems to reflect the significant resource investments required to adopt and implement not only SaMD, but the broader scope of workflow and process improvement software and related technologies. These investments extend beyond procurement of a software license and include cybersecurity updates, staff training, and hardware procurement. While these costs are typically considered indirect and therefore not reimbursable, we encourage the agency to consider how they might be incorporated into annual market basket updates or other update factors to ensure appropriate accounting for provider costs. Given the new and innovative nature of SaMD, we recommend CMS consider payment policies that are harmonized across payment systems and reflect that many of these

technologies may lack historical claims data. As one option, CMS may consider utilizing G codes for supply of SaMD and the associated monitoring. This approach, which the agency has already similarly implemented in its DMHT payment policy, would apply to SaMD that have an FDA indication, have undergone rigorous clinical and safety reviews, and include quality controls. The physician could procure the license, prescribe to the patient, and receive reimbursement.

In addition to bringing consistency to payment, this approach would further allow CMS to recognize the critical and distinct value of the different types of SaMD. Technologies designed for chronic care management, preventative care, and early diagnosis are all vastly different with varying costs and substantial potential value for patients, clinicians, and the health care system. We encourage the agency to implement payment policies that reflect the diversity of individual SaMD and the collective benefits these technologies offer.

3. Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Fee Schedule

The DME benefit category can be used for certain SaMD that meet the regulatory definition of DME. However, the current definition creates significant barriers to access under this program. We strongly recommend CMS revise its DME regulations to provide more specific direction for how digital therapeutic software technologies can be covered and paid under the program by:

- Clarifying DME coverage policies to reflect how digital therapeutics can be covered as DME;
- Revising accreditation standards for the special characteristics of SaMD;
- Aligning payment policy with the duration the SaMD technology is intended to be used;
- Ensuring distribution flexibility that supports patient access, understanding that transfer of title is not always appropriate or desired for these products; and
- Clarifying how the requirements within the statutory definition of DME apply to SaMD (e.g., recognizing that some digital therapeutic devices, which are regulated by the FDA as SaMD, have a three-year extended life but may not be appropriate for use by multiple individuals and thus may not be appropriate for rental).

4. Additional Considerations

a. *Accounting for AI-Enabled Devices that Streamline Operations while Improving Outcomes*

We further recommend that CMS consider alternative payment pathways for AI-enabled capital that can substantially reduce waste, enhance workflow efficiencies or improve patient quality and better outcomes including through medication management. Though inpatient settings may have historically conducted these internal value assessments, post-acute facilities including Skilled Nursing Facilities and Behavioral Health settings are limited in their capacity to adopt new technologies. We recommend that CMS work with industry, hospital, and pharmacy leaders to envision operational and clinical excellence with a reimbursement pathway to incent it.

b. *Accounting for Capital Investment in Standalone AI Technologies under Medicare's Payment Systems*

Despite the advancements in prevention, treatments and therapies, challenges to access and disparities in care persist in the US health system. Factors such as geographic inaccessibility, economics, insurance, QHP shortages, health system bias, race and ethnicity, language and many other factors contribute to this growing trend. In addition, for many conditions, access to evidence-based first line therapy is limited at best, reducing care quality, negatively impacting population health and increasing total health care costs. The very nature of SaMD provides opportunities to achieve access to evidence-based care at scale, especially for underserved populations. These innovative technologies are proven to deliver clinically effective treatment and allow for ongoing care to reach health care deserts where access to QHPs is challenged and where existing treatments fall short.

In addition to the SaMD recommendations discussed above, we encourage CMS to consider holistic updates to its fee for service payment systems to reflect the significant resource investments required to adopt and implement not only SaMD, but the broader scope of workflow and process improvement software and related technologies. These investments extend beyond procurement of a software license and include cybersecurity updates, staff training, and hardware procurement. While these costs are typically considered indirect and therefore not reimbursable, we encourage the agency to consider how they might be incorporated into annual market basket updates or other update factors to ensure appropriate accounting for provider costs.

C. Data Privacy Regulatory Updates and Clarifications

1. "Health Care Operations" under HIPAA

We recommend amending the definition of "health care operations" at 45 CFR § 164.501 to explicitly include AI model development and validation for the delivery, management, or improvement of health care services, with appropriate guardrails. The current definition of health care operations permits a HIPAA covered entity to perform specified activities without individual authorization, including "conducting quality assessment and improvement activities . . . provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities." Where the primary purpose of such activities is obtaining generalizable knowledge, the activity would instead be categorized as research, as defined at 45 CFR § 164.501. However, as HHS itself has recognized, the distinction between quality assessment and improvement activities and research can be unclear. This is often the case in the context of product innovation, where the line between health care operations-type improvements and research and development can be difficult to discern. When evaluating activities that fall within this gray area, covered entities must choose between following HIPAA's research rules, which require the entity to obtain certain permissions and take additional compliance steps, thereby delaying initiation of the activity, or risking enforcement exposure if a regulator disagrees with the covered entity's conclusion that the activity qualifies as health care operations.

Proposed language: Amend paragraph (1) of the definition of "health care operations" in 45 CFR § 164.501:

> ***Health care operations*** means any of the following activities of the covered entity to the extent that the activities are related to covered functions:

> (1) Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; AI model development and validation for the delivery, management, or improvement of health care services; patient safety activities (as defined in 42 CFR 3.20); population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment.

The proposed modifications would help provide certainty to covered entities that encounter this ambiguity when developing and improving AI models used for specified health care purposes. It would also enable them to fast-track AI innovations by not subjecting lower-risk activities to the burdensome HIPAA research rules. In addition, with its purpose limitation, including by extending health care operations model development only to internal activities, the proposal maintains protections for individuals, requiring compliance with existing HIPAA rules where protected health information (PHI) is sought to be used for other purposes.

2. HIPAA De-Identification Safe Harbor Flexibility

We recommend enhancing the flexibility of the de-identification standard at 45 CFR § 164.514 by allowing Safe Harbor de-identified datasets to retain otherwise restricted indirect identifiers that are important for AI development. HIPAA provides two means through which PHI may be de-identified. The first is the Safe Harbor method, which requires the removal of specified data elements and the absence of actual knowledge that the remaining information can be used to identify an individual. The second requires a formal determination from a qualified expert that, based on an analysis meeting certain criteria, the risk of re-identifying an individual in the dataset is very small. Once data has been de-identified under either method, it is no longer subject to HIPAA's restrictions on the use and disclosure of PHI. This makes HIPAA de-identified data valuable for various purposes, including AI product development and training.

The Safe Harbor method is generally easier to apply, as it does not require specialized knowledge that most organizations do not have in-house. This allows internal teams to de-identify data as needed in the regular course of their operations. The expert determination method, however, usually requires organizations to engage a third-party expert, which demands valuable time, money, and other valuable resources. Notwithstanding, many organizations are forced to rely on the expert-determination method, given its flexibility, which provides a pathway to creating and using more valuable de-identified datasets. Under that method, an expert can deem a dataset as de-identified, even if it has data elements that could not be included under the Safe Harbor, provided the expert's analysis meets HIPAA requirements. Dates related to individuals (e.g., date of service) and zip codes are examples of data elements that HIPAA-regulated entities often identify as valuable for product development that must be excluded from a Safe Harbor de-identified dataset, and that often are approved through expert determinations.

Proposed language: Amend 45 C.F.R. § 164.514(b)(2) by adding paragraphs 45 C.F.R. §

164.514(b)(2)(iii) and (iv):

(b) ***Implementation specifications: Requirements for de-identification of protected health information.*** A covered entity may determine that health information is not individually identifiable health information only if:

. . .

(2) (i) The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

(A) Names;

(B) All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:

(1) The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

(2) The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.

(C) All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older;

(D) Telephone numbers;

(E) Fax numbers;

(F) Electronic mail addresses;

(G) Social security numbers;

(H) Medical record numbers;

(I) Health plan beneficiary numbers;

(J) Account numbers;

(K) Certificate/license numbers;

(L) Vehicle identifiers and serial numbers, including license plate numbers;

(M) Device identifiers and serial numbers;

(N) Web Universal Resource Locators (URLs);

(O) Internet Protocol (IP) address numbers;

(P) Biometric identifiers, including finger and voice prints;

(Q) Full face photographic images and any comparable images; and

(R) Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section; and

(ii) The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

(iii) Notwithstanding paragraphs (b)(2)(i) and (b)(2)(ii) of this section, a covered entity may determine that health information is not individually identifiable if it contains identifiers described in paragraph (b)(2)(iv), provided that the dataset contains only the minimum necessary of such data elements required for a specific AI development or training use case, is used only for such purposes, and the covered entity complies with paragraph (b)(2)(ii).

(iv) Identifiers listed in paragraphs (b)(2)(i)(B) and (b)(2)(i)(C) may be included in a de-identified dataset, in accordance with paragraph (b)(2)(iii).

The proposal seeks to relieve HIPAA-regulated entities of the burden of relying on expert determinations to create valuable de-identified datasets for model development and training. This would allow those entities to dedicate more resources toward efficiently creating and improving AI-enabled products that can enhance the experience and outcomes of patients and consumers, while mitigating potential risks associated with the re-identification of individuals in de-identified datasets. Under the proposal, only the minimum necessary indirect identifiers would be permitted in a Safe Harbor de-identified dataset, as required by the circumstances of a particular use case.

3. Use of AI to Process PHI for Treatment, Payment, or Health Care Operations

We recommend clarifying that it is permissible to process the minimum necessary PHI through a third-party generative AI tool for treatment, payment, or health care operations purposes, provided that certain conditions are met. In accordance with the HIPAA Privacy Rule at 45 CFR, Subparts A and E, HIPAA requires an individual to authorize uses and disclosures of PHI, unless an exception applies. Per 45 CFR § 164.502, one such exception allows PHI to be used and disclosed for treatment, payment, and health care operations. A HIPAA covered entity may disclose PHI to service providers, known as business associates, for these purposes, provided that certain contractual requirements are in place and the business associate does not use or disclose PHI for its own purposes. However, given the ways in which generative AI tools process data and iteratively improve and learn, it is not always clear to covered entities whether PHI may be input into generative AI tools, even where the developer of the tool intends to serve as a business associate and has established safeguards to protect the confidentiality of PHI.

Uncertainty about the permissibility of HIPAA-regulated entities using these tools, which are

routinely leveraged in other sectors, could chill adoption and delay the health care industry's realization of their benefits. Thus, it would be helpful to clarify that where PHI is processed through a generative AI tool for treatment, payment or health care operations, only the minimum amount of PHI is processed for such purposes, and there is limited risk of the PHI being used or further disclosed for other purposes, given zero-day retention or similar controls, this qualifies as a permissible use and disclosure of PHI under HIPAA. Notably, this offers individuals additional protections in the treatment context, given that the current HIPAA rules do not require a health care provider's disclosure for treatment purposes to meet the minimum necessary standard.

Proposed guidance: HHS should issue an FAQ or other guidance clarifying the permissibility of these activities to avoid a situation where the lack of regulatory clarity may delay AI adoption, increase compliance costs, and slow innovation.

4. Patient Rights

We recommend clarifying that an individual's rights with respect to their PHI are subject to a reasonableness standard. HIPAA provides individuals with multiple rights regarding their PHI, as specified at 45 CFR §§ 164.522–164.528, including rights to access, amend, or receive an accounting of disclosures of their PHI. When an individual exercises these rights, their requests may cover information dating back as many as six years. Upon receipt of an individual rights request, a HIPAA-regulated entity must timely review certain of its systems for responsive records, and action the request as appropriate.

The rules granting these rights were written decades ago, and did not contemplate the sophistication and complexity of modern AI technologies. It can be difficult and time-consuming for an organization to validate where data resides within such systems, and to produce the requested information or make requested changes. This challenge is compounded as organizations deploy AI systems that interconnect, such as multi-agent systems, and that process and share data in ways that can be difficult to track and document. Amending the rules to require reasonable efforts to respond to individual rights requests would recognize the practicalities organizations face when responding to these requests, while still honoring the individual rights set out under HIPAA.

Proposed guidance: HHS should issue guidance clarifying that a HIPAA-regulated entity's reasonable efforts to action an individual's request to exercise rights with respect to PHI processed by an AI system satisfy the entity's obligations under HIPAA. This can help avoid applications of HIPAA rules that hinder beneficial AI uses.

5. How can HHS best support private sector activities (e.g., accreditation, certification, industry-driven testing, and credentialing) to promote innovative and effective AI use in clinical care?

We believe HHS can most effectively support private sector activities by prioritizing the development and use of consensus-based standards rather than imposing new regulatory expectations such as third-party evaluation infrastructures for AI tools. Consensus standards developed through accredited bodies provide a flexible yet rigorous foundation for testing,

accreditation, and certification activities without unnecessarily exposing proprietary methods or increasing compliance costs. Such standards can guide voluntary industry-driven testing, support credentialing efforts, and foster interoperability in a way that aligns with private sector innovation imperatives and real-world needs.

7. Which role(s), decision maker(s), or governing bodies within health care organizations have the most influence on the adoption of AI for clinical care? What are the primary administrative hurdles to the adoption of AI in clinical care?

A. Regulation of AI-Enabled Medical Devices

Maintaining the U.S. Food and Drug Administration (FDA) as the sole federal regulator of medical devices is essential to protecting patients while supporting continued innovation. FDA has decades of experience overseeing medical devices through a risk-based, lifecycle approach that already accounts for software, machine learning, and AI-enabled technologies. Creating additional or parallel regulatory requirements at other federal agencies would be duplicative, confusing, and inefficient; increasing compliance burden for industry and resource strain for regulators without improving safety. Fragmented oversight risks inconsistent standards, delayed patient access to beneficial technologies, and uncertainty for manufacturers and healthcare providers. Policymakers should reinforce FDA's primary authority over medical devices and ensure that cross-agency AI initiatives defer to FDA where medical devices are concerned, rather than introducing new regulatory layers that undermine an established, effective framework.

B. American Medical Association (AMA) Current Procedural Terminology (CPT) Hurdles

The CPT code set, maintained under the authority of the AMA, is the de facto language for reporting medical services and procedures across the U.S. healthcare system. Payers—including Medicare, Medicaid, and commercial insurers—and providers rely on CPT codes to describe the procedure performed, measure utilization, and set payment rates. Because CPT serves as the backbone for billing, clinical documentation, reimbursement, health information exchange, and utilization analysis, having an accurate and appropriate CPT code is often a prerequisite for widespread adoption of any medical service or technology, especially for new technologies that don't resemble traditional clinician-performed procedures.

AI and digital health technologies face unique hurdles in obtaining CPT codes that appropriately reflect the technology itself and/or the resources required for the accompanying service. Category III codes, where those early AI tools that have been able to obtain a CPT code have landed, are often considered "experimental and investigational" by payers and therefore either not reimbursed or reimbursed at rates far below the actual cost of the procedure and technology. Transitioning from a Category III code to a Category I code often requires demonstrating "widespread clinical use" and presenting strong clinical evidence, which can take years to develop even after FDA market authorization. These limitations result in codes that often lag behind real-world innovation, which slows commercial adoption of these technologies, limits clinician use, and adversely affects investment in next-generation technologies based on a lack of clear reimbursement pathways.

Recently, the AMA's Digital Medicine Coding Committee (DMCC) proposed a potential new coding framework, called "Clinically Meaningful Algorithmic Analyses" (CMAA) defined as "is a mechanism to codify algorithmic analysis of clinically relevant patient data (e.g., biophysical signals, imaging data, lab results) to produce clinically meaningful output or conclusions that impact patient care."[11] While we appreciate AMA's continued engagement with industry on this proposal, we remain concerned about the impact of creating a differentiated code set for algorithmic analyses without a defined pathway to coverage and payment. Shoehorning AI services into this proposed CMAA code set without a clear payment pathway could stifle innovation and investment in this space. Algorithm-only services that would potentially fall under the CMAA code set as drafted exist in other sections of CPT and have received coverage and payment under the Physician Fee Schedule (PFS), Hospital Outpatient Prospective Payment System (OPPS), or Clinical Laboratory Fee Schedule (CLFS). Creation of new code set without a defined pathway to coverage and payment not only jeopardizes new technologies but risks disrupting coverage and payment for existing services. As AMA continues conversations around a potential CMAA code set, we strongly urge CMS to take a more active role in ongoing conversations around coding for AI and digital health technology-enabled procedures, and to consider use of its own code creation authorities where appropriate to ensure timely reimbursement for these technologies.

8. Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care?

We see interoperability as critical for unlocking the full potential of AI in clinical settings. Enhanced interoperability across health systems and platforms would reduce data fragmentation and enable richer, more representative datasets for training and validating AI models. Specifically, standardization of clinical data formats and exchange protocols that preserving patient privacy protections would accelerate research and model development by making it easier to aggregate and harmonize data across diverse sources.

Preserving key clinical elements in de-identified datasets (such as age, gender, diagnoses, and outcomes) while maintaining privacy safeguards would expand the utility of data for AI research without compromising confidentiality. In addition, interoperability efforts grounded in consensus standards can facilitate benchmarking of model performance, support comparative evaluations across systems, and ultimately broaden market opportunities by enabling tools to perform reliably in varied care environments.

10. Are there specific areas of AI research that HHS should prioritize to accelerate the adoption of AI as part of clinical care?

We believe HHS should prioritize research that supports the development of international consensus standards and regulatory science tools that promote regulatory efficiency and the development of trustworthy and effective AI-enabled devices.

[11] American Medical Association. CPT® workgroups and committees. American Medical Association. Updated February 2, 2026. https://www.ama-assn.org/about/cpt-editorial-panel/cpt-workgroups-and-committees

a. Are there published findings about the impact of adopted AI tools and their use clinical care?

FDA has authorized over 1,300 AI-enabled medical devices that leverage the transformative power of AI to improve the patient experience and enable clinicians to better understand diseases, achieve faster, more accurate diagnostic results, and determine appropriate treatment pathways. Illustrative examples of how patients and clinicians benefit from incorporating AI-enabled technologies into clinical care are highlighted in AdvaMed's AI Policy Roadmap[12] and Advancing Patient Care: AI in Medical Devices document[13]. We additionally offer the following specific examples of AI-enabled devices with accompanying resources that quantify the impact and benefits of these devices when used in clinical care:

- Medtronic's GI Genius™ intelligent endoscopy module is a computer-aided detection system that uses AI to identify pre-cancerous and cancerous polyps in real-time during colonoscopies, assisting physicians in reducing the rates of missed polyps. There are over 30 publications, including 8 randomized controlled trials (RCTs), that demonstrate the clinical impact of the GI Genius™ module.[14]
- Stryker's Triton device incorporates an AI tool designed for estimating surgical blood loss, most commonly applied in obstetric procedures. This technology provides a real-time, quantitative method to estimate blood loss during surgery, offering advancement over traditional gravimetric and visual assessment methods. Rapid and accurate estimation of blood loss can enable the clinical care team to make more informed and timely decisions regarding postpartum hemorrhage (PPH) management and treatment protocols. Published studies demonstrate that implementation of the quantitative blood loss estimation can improve accuracy of blood loss estimation compared to gravimetric and visual techniques.[15,16] Reported clinical outcomes include an increase in the detection

[12] AdvaMed's AI Policy Roadmap (2025): https://www.advamed.org/wp-content/uploads/2025/03/AI-Policy-Roadmap.pdf
[13] AdvaMed's Advancing Patient Care: AI in Medical Devices document (2025): https://www.advamed.org/wp-content/uploads/2026/02/Advancing-Patient-Care-AI-in-Medical-Devices.pdf
[14] https://www.medtronic.com/content/dam/medtronic-wide/public/united-states/products/digestive-gastrointestinal/gastrointestinal-artificial-intelligence/gi-genius-intelligent-endoscopy-module-infographic-info-sheet.pdf
[15] Doctorvaladan SV, Jelks AT, Hsieh EW, Thurer RL, Zakowski MI, Lagrew DC. Accuracy of Blood Loss Measurement during Cesarean Delivery. *AJP Rep*. 2017 Apr;7(2):e93-e100. doi: 10.1055/s-0037-1601382.
[16] Rubenstein AF, Block M, Zamudio S, Douglas C, Sledge S, Tully G, Thurer RL. Accurate Assessment of Blood Loss during Cesarean Delivery Improves Estimation of Postoperative Hemoglobin. Am J Perinatol. 2019 Mar;36(4):434-439. doi: 10.1055/s-0038-1669397.

rate of PPH after cesarean sections compared to use of visual blood loss estimation,[17,18] as well as possible reduction in transfusion dose and shorter length of stay.[13]

As the U.S. Government seeks to ensure AI-enabled products across healthcare are used safely, we appreciate the opportunity to provide feedback on regulatory priorities and recommendations impacting medical technologies. AdvaMed member companies take seriously the trust patients place in them and have consistently acted to identify best practices balancing innovation with patient protections. Thank you for the opportunity to submit these comments. Please consider AdvaMed as a resource while you continue to consider regulations related to AI and medical devices.

Thank you for your consideration of AdvaMed's comments. Please do not hesitate to contact us with any questions using the contact information below.

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[17] Rubenstein AF, Zamudio S, Al-Khan A, Douglas C, Sledge S, Tully G, Thurer RL. Clinical Experience with the Implementation of Accurate Measurement of Blood Loss during Cesarean Delivery: Influences on Hemorrhage Recognition and Allogeneic Transfusion. *Am J Perinatol.* 2018 Jun;35(7):655-659. doi: 10.1055/s-0037-1613675.
[18] Katz D, Wang R, O'Neil L, Gerber C, Lankford A, Rogers T, Gal J, Sandler R, Beilin Y. The association between the introduction of quantitative assessment of postpartum blood loss and institutional changes in clinical practice: an observational study. *Int J Obstet Anesth.* 2020 May;42:4-10. doi: 10.1016/j.ijoa.2019.05.006.