COLLEGE of AMERICAN PATHOLOGISTS

February 23, 2026

The Honorable Jim O'Neill, MA
Deputy Secretary
Office of the Deputy Secretary
U.S. Department of Health and Human Services
200 Independence Ave., SW,
Room 614G
Washington, DC 20201

The Honorable Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201

Re: Request for Information: Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care (HHS Health Sector AI RFI) [Docket No. HHS-ONC-2026-0001]

Submitted via Electronic Submission to www.regulations.gov

Dear Deputy Secretary O'Neill and Assistant Secretary Keane,

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Request for Information (RFI) *Accelerating the Adoption and Use of Artificial Intelligence as Part of Clinical Care* issued by the Department of Health and Human Services (HHS) Office of the Deputy Secretary in collaboration with the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

As physicians specialized in the diagnosis of disease through laboratory methods, pathologists deliver high-quality diagnostic services to patients and other physicians. Pathologists place patient safety and test validity foremost in their minds as they determine which tests to implement in the clinical laboratory. The CAP's comments in response to this RFI are informed by its commitment to ensuring that patients receive the right test, at the right time, and with the right result. As a Clinical Laboratory Improvement Amendments (CLIA)-deemed accrediting organization and as a leading provider of laboratory proficiency testing/external quality assessment (PT/EQA), the CAP accredits over 8,300 laboratories and regularly introduces new PT/EQA programs to elevate the quality of laboratory medicine. The CAP Accreditation Checklists require the laboratory director to ensure that

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the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing, including AI and machine learning algorithms.

To accelerate the adoption and use of AI in pathology and laboratory medicine, the CAP recommends taking into account the

- Importance of manufacturer transparency regarding AI tools,
- Essential and complementary roles of Food and Drug Administration (FDA) review of AI-enabled medical devices and software and CLIA oversight of laboratories,
- Lessons from the CAP's work in laboratory accreditation that can be applied to AI, and the
- Importance of pathologists playing a leadership role in the use of AI systems in the laboratory.

The CAP will respond to selected questions applicable to its members' expertise in laboratory medicine and AI oversight.

CAP Responses to RFI Questions

Regulation
HHS seeks feedback on how current HHS regulations impact AI adoption and use for clinical care.

CAP Response: *Currently, CLIA and the FDA serve complementary and necessary roles in the adoption and use of AI for clinical care. FDA review is necessary to ensure safety and efficacy in a premarket setting and ongoing postmarket analysis. Following CLIA requirements, laboratories verify and validate local test performance prior to implementation, as well as perform and document calibration verification procedures every 6 months to ensure ongoing test validity.*

Pathologists are the physician leaders of clinical laboratories with responsibility for oversight of clinical and anatomic pathology laboratories. The decision about whether to implement an in vitro diagnostic device in the laboratory begins with careful review of the FDA-approved device label. Assessing AI devices prior to laboratory implementation requires transparent, comprehensible information from device developers about the model development data, performance data, performance metrics, performance monitoring, limitations, installation and use, and customizable features. Implementation challenges for AI systems include use of potentially imbalanced datasets for training; training data that does not accurately reflect the intended deployment context; and overfitting, which can cause a model to perform exceptionally well on training data but fail to generalize effectively to new, unseen data, producing an inaccurate output. The implementation of safeguards against these challenges in AI implementation will enhance physician utilization of AI systems. FDA review helps ensure these safeguards.

In the CAP's April 2025 comments filed in response to the FDA draft guidance "Artificial Intelligence Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations" [Docket No. FDA-2024-D-4488], the CAP encouraged the FDA to create a

requirement that manufacturers add to labeling information about the verification process and a set of target verification metrics that have a clear relationship to clinical performance.[1] Moreover, for AI-enabled devices that are iteratively modified, including by learning from real-world data, pathologists depend on transparent information from the "Predetermined Change Control Plan" (PCCP) that the FDA has noted can be included in a marketing submission for an AI-enabled device.[2]

After reviewing the FDA labeling and before using a test to report patient results, CLIA requires that pathologists demonstrate that the laboratory can obtain performance specifications with the device that are comparable to those established by the manufacturer for accuracy, precision, and the reportable range of test results for the test system.[3] CLIA also requires that pathologists verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. After implementing a test, laboratories must continue to monitor how it performs. Every 6 months, CLIA requires that laboratories conduct and document calibration verification to substantiate the continued accuracy of the test system throughout the laboratory's reportable range of test results for the test system.[4]

To summarize, CLIA complements FDA review by specifying high-quality practices in the laboratory that go beyond operational requirements defined by a manufacturer of an AI-enabled medical device and approved by the FDA. Pathologists use their experience as CLIA laboratory directors and section directors to ensure that FDA-cleared/approved AI devices are used appropriately, as the inappropriate implementation of any FDA-cleared device can result in harm to patients. While CLIA regulations are not directly applicable to other medical specialties, they may inform thinking about performance quality goals related to AI, which will ensure that the increased use and adoption of AI benefits patient care. Because AI-enabled tools must be safe, reliable, and clinically valid to gain physician trust and be adopted at scale, CLIA's longstanding quality framework provides an existing, proven system HHS can leverage to accelerate AI adoption, thereby reducing uncertainty, strengthening trust, and streamlining safe implementation.

Reimbursement

HHS seeks feedback on payment policy changes that ensure payers have the incentive and ability to promote access to high-value AI clinical interventions, foster competition among clinical care AI tool builders, and accelerate access to and affordability of AI tools for clinical care.

CAP Response: *AI-enabled clinical services have the potential to improve patient care but are likely to increase overall health care spending due to significant implementation and ongoing operational costs. AI also tends to expand clinical services rather than replace physician work by identifying*

[1] Please see the CAP's comments here: https://www.regulations.gov/comment/FDA-2024-D-4488-0037.
[2] As the FDA final guidance *Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions* notes, a PCCP generally includes a detailed description of the specific, planned device modifications, which is referred to as the "Description of Modifications"; 2) the associated methodology to develop, validate, and implement those modifications in a manner that ensures the continued safety and effectiveness of the device across the intended use populations, which is referred to as the "Modification Protocol"; and 3) the assessment of the benefits and risks of the planned modifications and risk mitigations, which is referred to as the "Impact Assessment." https://www.fda.gov/media/166704/download.
[3] 42 CFR 493.1253.
[4] 42 CFR 493.1255.

additional conditions and prompting increased downstream testing, consultations, and treatments. Within the CMS budget neutrality framework, these increased costs could place additional downward pressure on physician reimbursement. To avoid destabilizing physician payment and to preserve access to care, the CAP recommends that costs associated with AI technologies be treated as separate expenses outside of the Physician Fee Schedule.

The successful reimbursement of AI in clinical care depends on clear, predictable, and clinically appropriate payment pathways. Uncertainty regarding coding, coverage, and payment creates barriers to reimbursement and discourages adoption. The AMA CPT Editorial Panel plays a central role in establishing the coding structures that serve as the foundation for reimbursement policy, including the development of Appendix S, which classifies AI-enabled clinical services. In addition, ongoing work by the AMA-convened Digital Medicine Payment Advisory Group (DMPAG) and the Digital Medicine Coding Committee (DMCC) continues to develop recommendations for digital and AI services. The CAP recommends that HHS work closely with the AMA CPT Editorial Panel and its associated advisory groups and committees to establish a reimbursement framework that appropriately recognizes physician work, supports innovation, and ensures sustainable payment policies for AI-enabled clinical services.

Research & Development

HHS seeks input on ways in which HHS may invest in research & development (including public-private partnerships and cooperative research and development agreements (CRADAs)) to integrate AI in care delivery and create new, long-term market opportunities that improve the health and wellbeing of all Americans.

CAP Response: *The CAP supports infusion of new HHS funds in public-private partnerships, grants, or cooperative research and development agreements to integrate AI into the clinical laboratory and across healthcare organizations and provide a process for real-world evidence collection and analysis. The CAP has built the CAP AI Studio to provide our members with a safe, simulated space to explore cutting-edge AI tools used in pathology.[5] Additional HHS funds would help expand these efforts. From image analysis to diagnostic support, pathologists can interact with models in realistic patient scenarios prior to implementing these diagnostic tools in their clinical practice. This hands-on experience assessing AI systems prior to implementation is a key component of CLIA standards. Designed as both an educational tool and a discovery hub, the platform is a go-to destination for pathologists exploring AI in real-world contexts. This platform highlights the AI tools currently available and offers a glimpse of what's possible as we continue to investigate how AI can support and enhance the practice of pathology.*

In addition to this practical experience, federal support for public-private partnerships could help to develop high-grade datasets for validation across a variety of laboratory settings. Diverse, comprehensive datasets from multiple practices are necessary to validate the use of AI devices.

[5] https://newsroom.cap.org/latest-news/immersive-ai-platform-for-pathologists-set-to-launch-at-cap25-in-orlando/s/f72bb232-0294-430e-a734-7a55f4588894; https://www.cap.org/member-resources/councils-committees/informatics-committee/artificial-intelligence-pathology-resources#ai-studio.

These collaborations could also help to build trust and consistent approaches to practical implementation. Within the laboratory setting, we currently rely on the Clinical Laboratory and Standards Institute (a not-for-profit organization that develops consensus-based international laboratory standards and testing guidance) to develop clear guidelines and best practices for maintaining testing standards. Laboratory accreditation and proficiency testing also contribute to establishing and monitoring the quality of laboratory medicine. Pathologists are directly involved in setting the standards and quality maintained by the CAP's accreditation, proficiency testing, and guidelines programs. These guidelines, best practices, and educational materials standardize laboratory testing and enable local laboratory practitioners to appropriately monitor the quality of a wide variety of tests being performed in their laboratory. Measuring and evaluating AI based upon this foundation of laboratory practice helps ensure reliance on the proven safety, quality, and accountability systems laboratories already use.

In addition, the CAP has also collaborated with the FDA on the Systemic Harmonization and Interoperability Enhancement for Laboratory Data (SHIELD) collaboration. Laboratory data provides critical diagnostic information across the continuum of care, and AI technologies may assist with standardizing the data and integrating it in a more seamless way. SHIELD helped to address this problem by stimulating innovation by helping to build, implement, and support a comprehensive solution that addresses clinical and semantic device interoperability for in vitro diagnostics across the nation. Public-private partnerships such as SHIELD would better integrate AI in care delivery and create new, long-term market opportunities that improve the health and wellbeing of all Americans. The CAP would welcome additional opportunities like SHIELD to catalyze innovation to supplement the market.

Specific RFI Questions

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

CAP Response: *AI deployment in pathology is in early stages with relatively few AI models deployed in a limited number of laboratories. Some of the biggest barriers to the adoption and use of AI in clinical care and private sector innovation in AI for health care include the lack of understanding of how AI models are trained and developed, the uncertainty around the liability associated with use of AI systems, and the need for safeguards around AI systems.*

Transparent information for AI tools will resolve the lack of understanding of how AI models are trained and developed. For AI-enabled medical devices, the FDA's review process helps to provide this transparency. Transparency is essential to increase pathologists' and patients' trust in AI systems, making pathologists more willing to adopt and use AI in the pathology and laboratory settings. This will therefore accelerate private sector innovation in AI for health care. In addition, transparency will give pathologists greater confidence as to which AI models are trustworthy, thereby helping pathologists protect patient safety and avoid wasting time resources on unhelpful AI tools. Moreover, pathologists need transparency around whether AI tools are static or adaptive—that is, whether they are based on machine learning models with fixed ("static") parameters or whether they

continue to update after deployment ("adaptive").

Another barrier to physicians' willingness to use AI is that challenges in AI implementation exist and will require implementation of safeguards—such as transparency—to ensure identification and mitigation. For example, generative AI models can produce outputs that are not grounded in truth (a phenomenon often termed as hallucinations). Other implementation challenges for AI systems include use of potentially imbalanced datasets; training data that does not accurately reflect the intended deployment context; and overfitting. The implementation of safeguards against these challenges in AI implementation will enhance physician utilization of AI systems. The implementation of safeguards against these challenges in AI implementation will enhance physician utilization of AI systems and will make physicians more willing to use AI systems.

Another barrier to physicians' willingness to use AI is the uncertainty around the liability associated with use of AI systems, particularly for adaptive AI tools whose performance may change post-deployment. In laboratory environments, adaptive systems that update iteratively can drift from their originally validated purpose or introduce unintended interactions with connected instruments, software, or data pipelines (e.g., configuration changes or model updates that propagate across linked systems). Physicians should not bear sole liability for harms arising from such model-level risks. AI developers should also be held liable for harms from AI due to their knowledge about the design of those AI tools. A shared liability approach would encourage physicians to adopt and use AI, including pathologists employing AI in pathology and laboratory medicine.

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.

CAP Response:

Regulatory Policy: *In line with the CAP's response to question 1, the CAP recommends that HHS' federal AI policy supports manufacturer transparency of AI tools and ensures that physicians are not solely liable for the harms from AI. Consequently, the CAP suggests the following specific revisions to HHS regulations:*

- *Repeal 45 CFR 92.210 (Nondiscrimination in the use of patient care decision support tools),[6] which holds physicians accountable for discrimination caused by automated and AI-enabled patient care decision support tools. The HHS Office for Civil Rights (OCR) specified that patient care decision support tools include AI used to support clinical decision-making. This nondiscrimination provision places undue burden and responsibility on physicians to account for and address nondiscrimination that should be the responsibility of AI manufacturers that built and validated the AI model. Physicians do not create these patient care decision support tools, and it is the responsibility of the vendor that creates the models*

[6] Which was finalized in the Biden-era regulation Nondiscrimination in Health Programs and Activities (89 FR 37522).

to know whether the data that was used was discriminatory. The nondiscrimination provision as written will disincentivize AI use by physicians, as physicians are less equipped than AI vendors to detect the potential for discrimination.

- *The CAP urges HHS to maintain requirements for transparent information from AI developers regarding source attribute support, access, and modification and intervention risk management for predictive decision support interventions (DSIs), which include AI algorithms in ASTP's Health IT Certification Program.[7] ASTP is proposing[8] to rescind these informational requirements. However, as the CAP noted in 2023,[9] these informational requirements help guide pathologists in their responsibilities to assess AI systems. Specifically, these informational requirements help provide transparent information to pathologists about the development, deployment, and configuration of AI technology. This information helps pathologists apply their unique knowledge of laboratory testing in the implementation of AI-enabled devices in the laboratory, including ethical considerations, patient safety issues, risks, workflow, and other challenges. The CAP prioritizes patient safety and analytic and clinical validity in development and responsible implementation of AI in pathology. The information included in these requirements is important to promote trust in AI algorithms and encourage adoption and use of AI in pathology and laboratory medicine. Moreover, repealing these requirements would increase the risk of waste, fraud, and abuse proliferating in the healthcare system, as their repeal will make it more difficult for physicians to assess whether specific AI models are trustworthy.*

Payment Policy: *While AI has the potential to improve patient care, its rapid growth is also likely to increase overall health care spending. The implementation and ongoing operation of AI technologies introduce significant new and recurring costs, including investments in software, data infrastructure, cybersecurity, and continuous system updates. Moreover, AI is not a direct substitute for physician work in the clinical setting; instead, it tends to expand clinical care rather than replace existing services. AI can use enhanced diagnostic information to identify additional conditions, which in turn prompts more downstream testing, consultations, and treatments, ultimately driving higher overall utilization. These cost pressures are particularly problematic within CMS's budget neutrality framework, which requires that any increases in Medicare spending be offset by reductions elsewhere in the Physician Fee Schedule.*

To avoid destabilizing physician payment and undermining access to care, the CAP recommends that HHS consider establishing a policy approach in which costs associated with AI technologies fall outside the Physician Fee Schedule. Treating AI as a separate investment, rather than as a zero-sum adjustment within physician payment, would enable adoption of these technologies without exacerbating downward pressure on physician reimbursement.

3. For non-medical devices, we understand that use of AI in clinical care may raise novel legal and implementation issues that challenge existing governance and accountability structures (e.g., relating

[7] These requirements are in § 170.315(b)(11)(iv), (v), and (vi).
[8] In the *Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions To Unleash Prosperity* (HTI-5) Proposed Rule (90 FR 60970)
[9] https://documents.cap.org/documents/CAP-HTI-1-Comment-Letter.pdf.

to liability, indemnification, privacy, and security). What novel legal and implementation issues exist and what role, if any, should HHS play to help address them?

CAP Response: *Significant uncertainty exists for physicians about the liability involved in use of AI-enabled medical devices. Physicians rely on validated, reproducible results from medical devices to have confidence and trust in their use. Similar liability questions would emerge regarding use of non-medical devices, depending on how "non-medical device" is defined by HHS. A shared liability approach would encourage physicians to adopt and use AI, including pathologists employing AI in pathology and laboratory medicine.*

For privacy and security requirements, the Health Insurance Portability and Accountability Act (HIPAA) establishes national standards to protect individuals' electronic personal health information that is created, received, used, or maintained by a covered entity, including health plans, clearinghouses, and physicians and healthcare providers. HIPAA requires appropriate administrative, physical, and technical safeguards to ensure the confidentiality, integrity, and security of electronic protected health information. Depending on the type of healthcare information used and the intended use of the non-medical device, HIPAA concerns may certainly arise. We recommend that any issues with privacy and security surrounding non-medical devices be handled through HIPAA so as to avoid conflicting or duplicative requirements. This will help with implementation.

4. For non-medical devices, what are the most promising AI evaluation methods (pre- and post-deployment), metrics, robustness testing, and other workflow and human-centered evaluation methods for clinical care? Should HHS further support these processes? If so, which mechanisms would be most impactful (e.g., contracts, grants, cooperative agreements, and/or prize competitions)?

CAP Response: *AI models in medical devices or non-medical devices may undergo performance drift and must be monitored to ensure accuracy and patient safety. CLIA requires that laboratories assess medical device performance at least every 6 months and, in practice, internal and external performance assessment often occurs more frequently. Non-medical devices will also need ongoing monitoring to ensure robust performance.*

AI encompasses a broad range of machine learning techniques, from simple linear regression to complex deep neural networks, each with distinct assumptions, behaviors, and levels of interpretability. This diversity makes it challenging to define a single, standardized approach for establishing and maintaining AI trustworthiness, as different model architectures may require different validation and monitoring strategies. Consequently, the framework for measuring and evaluating the performance of AI in clinical diagnostics and non-medical devices should be relevant to the AI model and acknowledge the framework for oversight. This will ensure that users have the best information for verification and validity. Depending on the type of non-medical device, AI measurement and evaluation should also account for performance of AI in the local context and the stability of local input data.

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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?

CAP Response: *Implementation of AI systems will require development of standardized assessment and validation tools, as well as increased investment in the digital infrastructure of healthcare organizations. Federal support through the infusion of new funds and involvement in public-private partnerships will be important, such as through the FDA and the Advanced Research Projects Agency for Health (ARPA-H). The CAP would be pleased to be involved in this effort.*

The healthcare system routinely relies on independent, third-party accreditation, certification, and credentialing to set standards and measure performance. For example, the CAP's nationwide accreditation and proficiency testing programs form a foundational quality assurance infrastructure that can serve as a model for evaluating, monitoring, and safely deploying AI-enabled tools. Leveraging the CAP's programs will accelerate AI adoption by utilizing proven mechanisms that laboratories already trust and understand. The CAP's accreditation standards address conventional laboratory testing methods that share some features with AI systems. For example, the CAP accreditation requirements note that owing to potential drifts and shifts in performance over time, laboratories should establish controls, metrics, corrective actions, and procedures to address changes to the test system that could affect clinical results; such practices are similarly necessary for laboratories to implement with the use of AI -enabled medical devices.[10] *Similarly, at least twice yearly, CAP accredited laboratories must participate in external proficiency testing or conduct alternative performance assessments to demonstrate the continued accuracy of test results. AI systems must be monitored at least as frequently as conventional test systems to ensure ongoing acceptable performance.*

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?

CAP Response: *A primary hurdle to the adoption of AI in clinical care is the lack of transparent information from manufacturers about how AI models are trained and developed. In line with the CAP's response to question 1, the CAP notes that transparency of AI systems is crucial for resolving this lack of understanding. Transparency is essential to increase pathologists' and patients' trust in AI systems, making pathologists more willing to adopt and use AI in the pathology and laboratory settings. Transparency in the FDA-accepted labeling is essential. The CAP has encouraged the FDA to require that manufacturers add to labeling information about the verification process and a set of target verification metrics that have a clear relationship to clinical performance. With this information, pathologists verify and validate AI performance and advocate to institutional decision makers for investment in AI systems. Pathologists will be reluctant to use AI tools for which they lack adequate information about suitability for the tool's intended use. Pathologists also require clear information*

[10] Furtado LV, Ikemura K, Benkli CY, et al. *General applicability of existing College of American Pathologists accreditation requirements to clinical implementation of machine learning–based methods in molecular oncology testing.* Arch Pathol Lab Med (2025) 149 (4): 319–327.

about whether AI tools are static or adaptive as these characteristics have different implications for institutional oversight and ongoing monitoring. Pathologists will be more willing to adopt and use AI systems when transparent information is available and when those AI systems have appropriate safeguards in place. Put differently, physicians will ultimately be the ones to decide whether AI tools can be safely and appropriately integrated into clinical practice, as the adoption of AI for clinical care ultimately depends on whether these technologies meaningfully affect clinical decision-making and patient care. Accordingly, the CAP recommends that HHS work closely with the CAP and other medical societies to ensure that physician perspectives are incorporated into policies governing the adoption of AI for clinical care.

Healthcare systems typically have a committee of decision makers, which may include a chief information officer, with influence to make decisions about adoption of AI for clinical care. The challenge for pathologists is that these committees may not include pathologists, and decisions about AI implementation in a healthcare system would benefit from pathologists' input from their role as laboratory directors. CLIA requires that pathologists, as laboratory directors, assess AI systems prior to their implementation to verify performance in the local setting. Conducting this evaluation prior to purchase can be challenging. Because of this, the CAP built the CAP AI Studio to address this gap with a secure, web-based simulation environment that replicates a pathologist's digital workflow.[11] This initiative is about giving pathologists a trusted environment to evaluate new tools and stay in control of how technology fits into pathology practice. Federal support for these kinds of initiatives will help drive innovation and facilitate more rapid integration in clinical care.

Another administrative hurdle to AI adoption arises when coding, coverage, and payment pathways are unclear or misaligned. In the absence of established or well-defined CPT codes, there is uncertainty regarding documentation requirements, physician work attribution, and reimbursement. This uncertainty can delay or prevent adoption regardless of a technology's technical capability, making clear and predictable coding pathways a prerequisite for adoption.

Consequently, the AMA CPT Editorial Panel serves as a key external governing body influencing AI adoption by determining how AI services are classified, described, and coded. In 2022, the AMA CPT Editorial Panel adopted Appendix S into the CPT code set, which establishes the AI taxonomy for medical services and procedures. Appendix S was developed by the Digital Medicine Payment Advisory Group (DMPAG), a specialized workgroup convened by the AMA, and is used to classify AI-enabled medical services and procedures as assistive, augmentative, or autonomous based on the work performed by the AI application. Recognizing the growth in AI and other digital health tools, the AMA CPT Editorial Panel has also convened the AMA Digital Medicine Coding Committee (DMCC). The DMCC is currently developing comprehensive recommendations on coding, coverage, and payment for digital medicine. This includes discussions related to a new category of CPT codes for algorithmic services that do not include traditional interpretative physician or other qualified health care professional work. The new categorization for digital medicine codes will focus on the distinction

[11] https://newsroom.cap.org/latest-news/immersive-ai-platform-for-pathologists-set-to-launch-at-cap25-in-orlando/s/f72bb232-0294-430e-a734-7a55f4588894; https://www.cap.org/member-resources/councils-committees/informatics-committee/artificial-intelligence-pathology-resources#ai-studio.

between augmentative and autonomous services to account for and appropriately value physician work.

Through the combined efforts of the DMPAG and DMCC, the AMA CPT Editorial Panel can provide the clarity health care organizations need to adopt AI technologies within established regulatory and payment frameworks. Accordingly, the CAP recommends that HHS work directly with the AMA CPT Editorial Panel to establish a clear, consistent, and clinically appropriate coding framework that supports the responsible adoption of AI for clinical care.

8. Where would enhanced interoperability widen market opportunities, fuel research, and accelerate the development of AI for clinical care? Please consider specific data types, data standards, and benchmarking tools.

CAP Response: *The benefits of interoperability include wider availability of laboratory data at the point of patient care, reduction of redundant testing, decreased interpretation errors leading to unnecessary treatment or patient harm, and reduction in costs of system implementation and maintenance—all of these will accelerate the development, adoption, and use of AI for clinical care. With respect to the promotion of interoperability of laboratory data, regulations related to laboratory data interoperability should acknowledge and account for the limitations in pathologists' responsibility for and control of laboratory data once the data is reported to and/or finalized in downstream healthcare systems such as the EHR. Data exchange or provision requirements should use consistent, open (i.e., nonproprietary) standards and widely accepted coding terminologies. Moreover, regulations around laboratory data interoperability should incorporate financial support to assist laboratories with the cost of implementation. This is because the value of interoperable laboratory data accrues primarily to users of the data (that is, patients, clinicians, and public health policy makers), while the cost of standardization accrues to data creators (that is, laboratories). This disparity between cost and benefit should be addressed as part of the regulatory design to avoid imposing a financial burden on pathologists and laboratories. The CAP envisions that as AI systems improve, developers will be able to train them to transform existing multivariate data into standardized, clinically meaningful form, thereby avoiding considerable investment in standardizing data inputs. This standardization will enable greater use of important diagnostic data from the laboratory setting.*

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Thank you for the opportunity to submit these comments. The CAP looks forward to working with HHS to help promote high-quality AI implementation. To conclude, the CAP encourages the HHS to consider the unique insights from pathologists and laboratory medicine in its assessment in how it can accelerate the adoption and use of AI in clinical care. AI models must be transparent and explainable for pathologists to best fulfill their duties concerning AI—this transparency and explainability will increase the use of AI in laboratory medicine. The CAP stands willing to work with

the HHS to provide its members' perspectives as CLIA laboratory directors, section directors, and peer reviewers for the CAP's Laboratory Accreditation Program and how this experience can be applied to accelerating the adoption and use of AI in clinical care. Questions regarding AI regulation can be directed to Han Tran at htran@cap.org. Questions regarding AI reimbursement can be directed to Todd Klemp at tklemp@cap.org.

Sincerely,
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