

Association of American Medical Colleges 655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399 T 202 828 0400 www.aamc.org

Submitted via <u>www.regulations.gov</u>

June 16, 2025

Dr. Mehmet Oz Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-0042-NC 2500 Security Boulevard Baltimore, MD 21244 Dr. Thomas Keane Assistant Secretary for Technology Policy (ASTP) National Coordinator for Health IT (ONC) Department of Health and Human Services 200 Independence Avenue, SW Washington, DC 20201

Re: Request for Information; Health Technology Ecosystem (CMS-0042-NC)

Dear Administrator Oz and Assistant Secretary Keane:

The Association of American Medical Colleges (the AAMC) welcomes this opportunity to comment on the Request for Information; Health Technology Ecosystem, 90 *Fed. Reg.* 21034 (May 16, 2025), issued by the Centers for Medicare & Medicaid Services (CMS) and Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP/ONC).

The AAMC is a nonprofit association dedicated to improving the health of people everywhere through medical education, health care, biomedical research, and community collaborations. Its members are 160 U.S. medical schools accredited by the Liaison Committee on Medical Education; 12 accredited Canadian medical schools; nearly 500 academic health systems and teaching hospitals, including Department of Veterans Affairs medical centers; and more than 70 academic societies. Through these institutions and organizations, the AAMC leads and serves America's medical schools, academic health systems and teaching hospitals, and the millions of individuals across academic medicine, including more than 210,000 full-time faculty members, 99,000 medical students, 162,000 resident physicians, and 60,000 graduate students and postdoctoral researchers in the biomedical sciences. Through the Alliance of Academic Health Centers International, AAMC membership reaches more than 60 international academic health centers throughout five regional offices across the globe.

The AAMC applauds CMS and ASTP/ONC for their efforts to advance interoperability and improve the effective and responsible adoption of technology to empower patients and improve their health. We share the agencies' commitment to ensuring that patients and clinicians have the increased ability to access electronic health information to make informed health decisions through secure and seamless exchange of data. The focus of efforts to improve interoperability should be on what is needed for high quality clinical management of patients receiving care from providers as they move through the health care system. At the same time, it is critical to also protect the privacy and security of patient health information.

Many of the AAMC's member institutions were early adopters of electronic health record (EHR) technology; they have helped to pioneer its development and use and are committed to providing quality care using these systems. They are committed to broadly adopting evidence-based, clinically effective

digital capabilities to support patient care and experience. Our comments in response to the request for information on the state of data interoperability and broader health technology infrastructure follow.

REDUCE BURDENS THAT PREVENT BROADER ADOPTION OF DIGITAL HEALTH

Make COVID-19 Telehealth Waivers and Flexibilities Permanent to Reduce Uncertainty, Encourage Continued Investment, Improve Patient Access, and Prevent Unintentional Chilling Effect on Digital Health Innovation

Unless Congress acts, starting October 1, 2025, CMS will apply geographic limitations and limitations on the site of service where Medicare patients may receive telehealth services. The AAMC recognizes that CMS may not have the authority to waive these statutory limitations on telehealth services. CMS does possess the authority, however, to make permanent the waivers and regulatory changes established by CMS in response to the COVID-19 public health emergency (PHE) that have facilitated the widespread use of telehealth and other communication technology-based services, and in turn, that improve access to health care. The AAMC strongly supports these permanent waivers. If coverage of telehealth services is no longer in jeopardy of expiring, it will spur investment and innovation within the digital health community.

The AAMC also urges CMS to permanently change its regulations to permit practitioners to use their enrolled practice location instead of their home address when providing telehealth services from their home through CY 2025.¹ Requiring reporting of practitioner's home addresses for enrollment is likely to discourage practitioners from providing telehealth services from their home, limiting access to care. Additionally, practitioners have expressed privacy and safety concerns associated with enrolling their home address.

Remove Barriers to Uptake and Sustainability of Interprofessional Consults

In 2019, CMS finalized payment for six CPT® codes to recognize interprofessional consultations (99446, 99447, 99448, 99449, 99451, 99452). (83 FR 59452, 59491, November 23, 2018) The AAMC and its member health systems have found interprofessional consultations utilizing provider-to-provider modalities and peer-mentored care as an effective way to improve access to care. Patients benefit from more timely access to the specialist's guidance and payers benefit from a less costly service by avoiding the new patient visit with a specialist, not to mention likely downstream costs, when interprofessional consults take the place of a referral.

CMS requires that providers collect coinsurance from their patients when billing for CPT® codes 99451 and 99452. While the AAMC understands that CMS may not have the authority to waive coinsurance for CPT® codes 99451 and 99452 or GIPC5 and GIPC6 under the Medicare fee-for-service program, we remain concerned that the coinsurance requirement is a barrier to providing these important services for several reasons. First, given the structure of two distinct codes, patients are responsible for two coinsurance payments for a single completed interprofessional consultation, which predictably induces confusion. Interprofessional consultations are often used for patients with new or acute conditions who are not established within the consulting specialty's practice and therefore do not have an existing relationship with the consultant. A coinsurance bill for a service delivered from a provider that is unknown to the patient could cause them to believe a billing error has occurred. Another barrier is that

¹ 89 FR 97710, at 97762 (December 9, 2024)

Guidance for CPT® code 99452 clarifies that it should be reported by the treating physician/QHP for 16-30 minutes in a service day preparing the referral and/or communicating with the consultant. We recommend the guidance should be changed so that the time for these codes includes all the activities associated with the interprofessional exchange between the treating provider and consulting physician, including follow-through on the consultant's recommendations. This clarification would help to expand the use of these valuable services in the future and ensure from a program integrity standpoint that patients and payers are realizing the intended value of this service.

Realign Reimbursement Models to Recognize Clinician Effort When Leveraging Digital Health Tools

Leveraging digital health tools with their patients requires clinicians to deliver care that is not included in traditional fee-for-service reimbursement, which largely values only care that is delivered directly within a patient visit. Use of digital health tools still require clinicians to manage data inputs, evaluate data trends, and act on the data to make care referrals, prescribe appropriate therapies, and communicate information back to the patient. That care management, as with other care delivered outside of a patient visit, is not considered reimbursable clinical work in traditional reimbursement models.

There are also issues where CMS does adopt reimbursement codes to encourage physicians to leverage digital health tools for their patients. For example, remote physiological monitoring (RPM) services involve the collection and analysis of patient physiological data to develop and manage a treatment plan related to a chronic and/or acute health illness or condition. It allows patients to be monitored remotely while in their homes, and for providers to track patients' physiological parameters (e.g., weight, blood pressure, glucose) and implement changes to treatment as appropriate. Health care providers and their patients can experience many benefits from the use of RPM, including reduced readmissions, shortened hospital stays, improvements in quality of life, and lower costs. These services allow physicians to track their patients' health metrics without requiring multiple in-person visits from patients whose schedules cannot accommodate greater time commitments. Despite these benefits, these services have been underutilized, in part, due to payment policies.

One of the barriers to bill for RPM services is that for the initial set-up and continued monitoring codes, monitoring must occur during at least 16 days of a 30-day period. Expenses associated with configuring systems to capture necessary documentation and the actual clinician time spent documenting time spent per calendar month greatly outweigh Medicare reimbursement for these services. The 16-day requirement prevents providers from using these codes when clinical indications are that the patient would require less than 16 days of monitoring. Additionally, the 16-day minimum threshold for transmitted physiological data per 30 days undermines the value of time spent coordinating care and delivering needed services to patients who require monitoring less than 16 days in a 30-day period. Allowing fewer than 16 days of data transmission by a patient in a given month would greatly increase access to care and promote high value use.

Additionally, there has been a decrease to the Practice Expense Relative Value Units each year since RPM services were adopted for the Medicare Physician Fee Schedule in 2019. This means that clinicians who furnish these services receive less reimbursement to cover the cost of the device, even though the device price has not decreased. CMS should evaluate opportunities to realign physician reimbursement to directly compensate providers for the care delivered when they leverage digital health products.

Expand Fraud and Abuse Safe Harbors for Supporting Improved Access to Broadband and Digital Health Tools

In 2020, the HHS Office of the Inspector General (OIG) finalized new safe harbor protections under the Anti-Kickback Statute (AKS) that set out new opportunities for health care providers to engage and support patients to improve quality, health outcomes, and efficiency without violating the AKS prohibition on inducements.² Specifically, OIG established a new AKS Patient Engagement and Support Safe Harbor, that allows participants in value-based enterprises to furnish patient engagement tools and supports to a patient in a target patient population, as well as a pathway for device and medical supplies manufacturers to provide digital health technology. We have heard from members that this safe harbor does not allow them to reach all patients, due to its narrow scope to a value-based enterprise for a target patient population. Additionally, the safe harbor is limited to an aggregate retail value not to exceed \$500 (increased to \$605 for 2025³) and must advance one of five enumerated goals. We have heard concerns from members that they are still unable to support patients' access to broadband connectivity to support use of digital health tools or provide mobile devices to allow patients to use digital health apps without potentially implicating civil and criminal penalties under the AKS.

Clarify Patients' Privacy Protections for Digital Health Tools and Applications Not Subject to the HIPAA Privacy and Security Requirements

The AAMC broadly supports patient access to their own health information, using the digital health tools and apps of their choice. We are concerned that a patient may not understand that their information obtained through these apps may be shared with third parties that are under no obligation to keep that information private. Health information is very personal and there is potential for the information shared in apps to be used in ways that impact employment, access to affordable health insurance, or other areas. To date, CMS and ONC rules have not established any patient privacy and security protections or any standards regarding how the information from a digital health app may be used. Patients deserve transparency on their privacy rights and the protections they have for their private health data when they choose to access or exchange their health data through an app, especially those offered by entities not covered by the HIPAA.

IMPROVE HIGH QUALITY INTEROPERABILITY TO SUPPORT HIGH QUALITY CARE

Prioritize Improving Interoperability of Electronic Health Records (EHRs)

Broad interoperability for all data within the EHR to be accessible for exchange, regardless of format, across digital health products is a worthy long-term goal to support high quality patient care. In the short term, CMS and ASTP/ONC should prioritize general provider EHR to EHR interoperability. This fundamental level of interoperability is still a work in progress – where some members report a high reliance on their local health information exchange (HIE) to access, exchange, and use electronic health information (EHI) from providers with different EHR vendors. Providers also have challenges with interoperable exchange with providers outside of their health system on the same EHR platform. Improving EHR interoperability is a critical first priority towards high quality health data access and exchange.

² 85 FR 77684 (December 2, 2020).

³ HHS OIG, <u>Annual Inflation Updates to the Annual Cap on Patient Engagement Tools and Supports Under 42 CFR § 1001.952(hh)</u> (last updated October 11, 2024).

Empower Patient-Driven Interoperability to Share Clinical Information

Empowering patients to make informed medical decisions based on access to their own health information will help drive better health outcomes. To achieve this, patient data must be easy to access and intuitive to exchange. In addition to patient-centered interoperable systems, care navigators are also critical to help patients use this information to connect with all their providers across EHR platforms.

However, it is important to ensure that there is a clear distinction between interoperability that allows patients to access and share their own records versus access to business records (i.e., scheduling or appointment databases). Business records are uniquely tailored to each health system and practice and contain information that is specific to the management of the business. Providing external access to these records will not improve patient care. In fact, it may cause confusion because external viewers will not have access to internal policies and procedures and lack other necessary information to properly utilize the business records. Furthermore, business records are often evolving and changing, making it even more difficult for external viewers to use the information in a meaningful way. Health systems and their staff are best suited to review business records and disseminate information, when appropriate, in a format that can be easily digestible for external use.

Allow Providers to Control Which Data from Outside Sources, including Digital Health Apps, and Medical Devices is Valid, Reliable, and Clinically Meaningful to Integrate into the Medical Record

With greater interoperable exchange of health data, providers are concerned that they will not be able to manage data from outside sources and to ensure that data generated outside of traditional health care delivery from digital health apps and devices is valid and reliable for clinical use. As more and more data can be pushed into a provider's EHR, clinicians will need to be able to efficiently manage signal-to-noise and discern what is clinically relevant. Clinicians and healthcare systems, as custodians of the legal medical record, must have the ability to determine which data is ultimately integrated into a patient's medical record.

Lead Efforts to Develop an Interoperable National Directory of Healthcare Providers & Services

There is a great need to improve healthcare provider information within health plan directories to ensure they contain accurate information for patients while reducing the burden on providers to submit and update the information included. Health plan directories are often the first source used by patients to identify healthcare providers and check whether a clinician is within their health plan's network and taking on new patients. But too often, health plan directories contain outdated or even erroneous information, frustrating, or even harming patients.⁴ The AAMC strongly supports efforts to build stakeholder consensus to inform the future development of a centralized solution to improving health plan directories to improve patient experience and reduce burden for providers.

Ensuring success of a National Directory of Healthcare Providers & Services (NDH) will require careful consideration and stakeholder consensus on the following design elements: a core agreement of what types of "listed entities" (i.e., individuals and groups of providers) should be included in the NDH, a core set of standardized data elements (including definitions for those elements), and core functionality for

⁴ R. Pifer, <u>Centene sued over alleged ghost network following member's death</u>, Healthcare Dive (June 3, 2025).

updating information, including the ability for providers to delegate directory maintenance. Please refer to our comments to CMS on the Request for Information on an NDH in 2022 for more detail.⁵

Ensure Any Future Policies to Use Digital Identity Credentials to Access Patient Portals to Mitigate Potential Unintended Consequences

Currently, patients must create new profiles and login credentials to access each health care provider's patient portal, when treated by providers across health systems. This requires the patient to track each login for each provider relationship and may lead to frustration and challenges accessing their own health information. Over time, broader digital identity credentials (for example, CLEAR, ID.me, Login.gov, and other NIST 800-63-3 IAL2/AAL2 CSPs) have entered the marketplace and could be a solution to reducing burden on patients accessing multiple provider portals. However, the AAMC recommends that CMS and ASTP/ONC fully vet the benefits and risks of using policy levers to increase adoption of digital identity credentials. Broad, system-agnostic digital identity credentials could introduce cross-system vulnerabilities if breached (unlike unique logins for each provider system). Additionally, requiring use of digital identity credentials could reduce access for those patients unable or unwilling to obtain such a credential (due to cost, with private marketplace systems, or reduced trust in such systems) as well as add burdensome costs to health care systems and providers to adopt (through fees set by the companies that administer them).

Improve Patient Matching Solutions to Improve Patient Safety

Patient matching remains a critically important component of interoperability as providers must be able to accurately match a patient to his or her data from outside sources (digital health tools, apps, and devices). Patient matching continues to be a barrier and often requires manual intervention due to incomplete or inconsistently formatted demographic information that is utilized to match patient records. Matching errors can lead to adverse events that seriously compromise a patient's safety. We recommend that CMS and ASTP/ONC work with stakeholders to explore best practices for patient matching. We support the ongoing work of ONC and others on identifying patient matching solutions to promote interoperability.

Thank you for the opportunity to comment on this request for information, and hope that it is the start to ongoing dialogue with CMS and ASTP/ONC on improving access and use of evidence-based, clinically relevant technology to improve patient health and well-being. If you have questions regarding our comments, please feel free to contact my colleagues Phoebe Ramsey (pramsey@aamc.org) and Ki Stewart (kstewart@aamc.org).

Sincerely,

In 3 m

Jonathan Jaffery, M.D., M.S., M.M.M., F.A.C.P. Chief Health Care Officer Association for American Medical Colleges

Cc: David J. Skorton, M.D., AAMC President and Chief Executive Officer

⁵ AAMC, <u>Comments to CMS Regarding a National Directory of Healthcare Providers & Services</u> (December 6, 2023).