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June 16, 2025

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Request for Information; Health Technology Ecosystem

Dear Dr. Oz,

The American Osteopathic Association (AOA), on behalf of the more than 197,000 osteopathic physicians (DOs) and osteopathic medical students we represent, appreciates this opportunity to provide input on CMS' effort to improve access to innovative digital health products and enhance interoperability in Medicare. We share the Administration's goal of advancing policies that will foster innovation, drive nationwide data interoperability, and ensure that patients and physicians have access to cutting edge technologies.

Improved interoperability and innovation in digital health technology, including AI-driven technologies, will improve patient care through promoting better outcomes, increasing efficiency, supporting physician decision-making, and enabling physicians to spend more time with patients. Osteopathic physicians, who are trained in patient-centered, whole-person care, play a critical role in fostering innovation, whether through development of new technologies, leading product adoption and implementation in their care settings, or using innovative care tools in their practice. It is with this perspective that we provide feedback on questions within CMS' RFI as outlined below.

Patient Needs

What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process?

A consistent federal approach to evaluation of digital health products is needed to ensure safety and efficacy, and appropriate use of federal resources. A broad range of products fall under the term "digital health products", which encompasses clinical decision support software, digital therapeutics, connected health and remote monitoring tools, and consumer facing mobile applications for health management. Overall, we support the existing regulatory framework whereby products that qualify as devices are regulated by FDA, and tools that qualify as health IT are certified by the certification program under the Office of the National Coordinator ONC for Health IT (ONC).

In regard to products that qualify as health IT, we believe that ONC should expand its certification program to encompass a broader range of products and functions, including products that support prior authorization, benefit checks, and various application programming interfaces. For products that meet the FDA's definition of a medical device and must receive FDA clearance to be marketed, we believe that FDA should maintain oversight of these products and the current framework, whereby CMS makes a coverage determination following FDA clearance, should be continued.

A broad range of products fall under FDA's definition of a "software as a medical device", including clinical decision support tools, prescription digital therapeutics, remote monitoring products, risk management tools, and numerous other technologies. Currently, there are significant gaps in FDA's oversight, as well as in developers' transparency regarding their software's performance. Several studies have been published in recent years indicating that the current "risk based" regulatory framework for evaluating and approving AI devices may be inadequate, and that many products may not be sufficiently tested and validated. Although FDA has approved over 950 medical devices driven by AI, as many as 43% lack clinical validation data in their FDA

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submissions,[1] and at least 211 products have been recalled.[2] A stronger regulatory framework that supports positive patient outcomes is essential. **FDA should pursue standardized regulatory mechanisms requiring transparency in AI device development, validation of datasets, and continuous monitoring of products post-approval to ensure ongoing safety, efficacy, and bias mitigation. Until this process is improved, it is particularly important for CMS to develop a more systematic process for evaluating digital health products and determining whether to cover such products based on their performance.** CMS must be judicious in use of federal resources, and while some products hold tremendous promise for improving health outcomes, products that are not rigorously validated and that have little evidence of improving outcomes may not merit coverage.

Similarly, many AI-driven software tools used by enterprises in operations, but do not meet FDA's device definition, lack appropriate oversight. However, these products can still result in erroneous or inappropriate outcomes that harm patient care. Such products include patient population management and prior authorization decision tools used by payors. We strongly urge FDA to use existing authority to better regulate these products, and if it lacks authority, to work with Congress to ensure appropriate oversight.

We also wish to highlight that AOA is working closely with the Digital Medicine Society (DiMe) on an evaluation framework for AI-enabled products and has convened a panel of experts focused on these issues. These experts include developers, health system leaders, and leaders in medical education focused on innovation. **We welcome the opportunity to work more closely with the Administration on this effort and share technical input where helpful.**

Data Access and Integration

In your experience, what health data is readily available and valuable to patients or their caregivers or both? What are specific sources, other than claims and clinical data, that would be of highest value, and why?

Exchange of a broader range of data types can support more efficient care delivery, access to drugs and services, and greater transparency for patients as they seek care. CMS and the Assistant Secretary for Technology Policy (ASTP) should advance standards that promote the exchange of health plan data, such as benefit information prior authorization data, to make it available to both patients and physicians at the point of care.

1. **Prior Authorization Data:** Prior authorization (PA) places substantial time and cost burden on physician practices, and care delays associated with PA often lead to serious adverse events among patients. PA requirements can create unique challenges for small, independent practices which have more limited staff, time, and financial resources, resulting in time being taken away from patient care to comply with requirements. In recent years, MA plans have increased their application of PA across nearly all medical items and services, with some of the most dramatic increases in patient exposure to PA taking place with psychiatric services; diagnostic procedures, labs, and tests; physician administered drugs; and inpatient hospital services.[3] Expanded use of PA has a direct impact on patient outcomes. In an American Medical Association survey, 88% of physicians report that PA interferes with care continuity, 94% report that PA results in care delays, and 78% report that PA leads to treatment abandonment.[4] CMS has taken substantial steps forward in recent years to address these issues, and we urge the administration to build on these efforts, including the success of the 2017 Patients over Paperwork Initiative. In 2024, ASTP issued a proposed rule that would have advanced standardized Fast Healthcare Interoperability Resource (FHIR)- based application programming interfaces (APIs) to support exchange of this information between payers, physicians, and patients. We urge CMS and ASTP to return to this work and finalize these proposals.

[1] Chouffani El Fassi, S., Abdullah, A., Fang, Y. et al. Not all AI health tools with regulatory authorization are clinically validated. Nat Med (2024).
[2] Muehlematter et al. "FDA-cleared artificial intelligence and machine learning-based medical devices and their 510(k) predicate networks." The Lancet Digital Health, Sep 2023
[3] Neprash and Mulcahy. "The Extent and Growth of Prior Authorization in Medicare Advantage." *Am J Manag Care. 2024;30(3):e85-e92.* Available here.
[4] American Medical Association. Prior Authorization Physician Survey. 2023. Available here.

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2. **Real-Time Benefit Data**: policies should empower physicians when partnering with their patients to deliver care that best meets their needs, and establishing a real-time pharmacy benefit (RTPB) standard will support broader adoption of real-time benefit tools. The availability of RTPB allows physicians to view information about patients' plan benefits, coverage, costs, and prior authorization requirements at the point of care, within the prescribing workflow. Low adoption of RTPB tools is largely due to "fragmented availability and implementation of tools across EHR vendors," and establishing new certification criteria within the ONC health IT certification program will help to address this issue.

The prior authorization process is complementary to the prescribing workflow. Within a single workflow, physicians should be able to begin the prescribing process, view formulary information (including drug tiers), review cost and coverage information, view prior authorization requirements, and submit prior authorizations. **The AOA believes that establishment of RTPB standards and adoption of patient, provider, and payer APIs for prior authorization and RTPB will help streamline the prescribing and prior authorization process and reduce administrative burden**.

What are the most valuable operational health data use cases for patients and caregivers that, if addressed, would create more efficient care navigation or eliminate barriers to competition among providers or both?

In addition to prior authorization and real-time benefit data, ensuring that patients have access to up-to-date plan directory information in a centralized resource is essential to supporting competition. In 2024, Medicare Advantage beneficiaries could choose from an average of 43 plans operating in their counties, the highest number of options available to beneficiaries since the creation of Medicare Advantage.[5] While the availability of a broad range of plan options enables beneficiaries to select plans that meet their individual needs, up-to-date information about plan networks is essential for them to make informed decisions.

When searching for an MA plan on the Medicare Plan Finder (MPF), beneficiaries can narrow down options using filters for plan benefits, insurance carriers, drug coverage, and star ratings. However, if the beneficiary would like to choose a plan that allows them to continue to see their current physician, the beneficiary must go to the plan's website and review the provider directory. If a patient sees multiple physicians and is considering several plans, the process of selecting a plan can be tedious and confusing when information is not in a single place. Beyond using directories in plan selection, up-to-date directories are essential to promoting competition in healthcare markets by ensuring that patients have accurate information on the range of providers they are able to access within their plan's network. When directories are not accurate, this can lead to delayed care, unexpected out-of-pocket costs, and an inability for patients to accurately compare provider options for non-urgent or elective services. **AOA urges CMS and ASTP to require directory information to be exchanged via standards-based APIs**.

Digital Health Apps

What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved (see description in PC-5) digital health products for their patients?

A key barrier to adoption of new digital health products is the cost of adoption and inadequacy of reimbursement, which we discuss further in our response to the question below. Rural communities in particular face pronounced challenges due to higher costs for delivering care, lower patient volumes, and more challenging payer mixes for their patient populations (e.g. greater share of Medicaid patients). These combined factors, which compound the challenge of inadequate overall payment in Medicare, make it difficult to invest in new technology and recoup the costs.

What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows, such as quality measurement reporting, clinical documentation, and billing tasks? How could these obstacles be mitigated?

To achieve wide adoption of innovative technologies across healthcare, physicians and enterprises must see return on investment for these products. How different software and devices are paid for varies by the nature of the product, and challenges exist

[5] MedPAC 2024 Report. Medicare Advantage. Available here.

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across payment systems and product use cases. Without a strong payment framework, adoption of innovative tools will occur inequitably across sites of care (e.g. physician practices vs. health systems), limiting access to innovative tools to sites of care that have more capital and can implement tools at scale.

Products that support operations, such as helping with population management or automating documentation and billing (e.g. ambient AI), are not separately billable under payment systems. Under the physician fee schedule specifically, these are considered practice expense, and CMS' current PE methodology does not fully account for these costs. Additionally, due to the slim margins that many physician practices operate under, practices often don't have sufficient capital to invest in these products even though they may improve patient care, enable them to spend more time at the bedside with patients, and help them better target practice resources. In addition to improving patient care, these tools can help address physician burnout, drive efficiency, and improve physicians' experience in delivering care.[6]

Tools that function as "software as a service" that are used in direct patient care and have an associated billable service can be paid directly under various payment systems. However, there are significant flaws in how payment is calculated which is driving inequitable adoption across sites. While hospitals receive separate payment for many of these tools, physicians under the physician fee schedule do not. Under the hospital inpatient prospective payment system, manufacturers can apply for a new technology add-on payment until payment for the new technology can be bundled in the payment rates for applicable Medicare severity-diagnosis related groups. In the hospital outpatient prospective payment system (OPPS), software as a service is often classified as a separately payable service, not ancillary or supportive to the bundled service the software is enabling. Under the physician fee schedule, CMS has not created national payment rates for most software, and payment is "carrier priced", relying on Medicare Administrative Contractors (MACs) to determine payment on a case-by-case basis. However, MACs lack sufficient data on product costs and often establish inadequate payment rates.

Prescription digital therapeutic products are generally those that are approved by the FDA to be prescribed by a physician to manage or treat an injury or disease. They are typically administered by patients themselves on a phone, tablet, smartwatch, or similar device, and they primarily use software to diagnose or treat an illness or injury. These devices do not fall into a defined Medicare benefit category and lack a clear payment mechanism, even though they may benefit patient care and improve outcomes.

A recent report by the Medicare Payment Advisory Commission highlights many of the issues described above. [7] While AOA's concerns primarily focus on Medicare, state coverage of these technologies under Medicaid programs is patchwork and often limited. The systemic problem of inadequate payment across payors limit adoption.

It is also important to note that physician services associated with "software as a service" cannot be leveraged for preventive care. This is because many services, such as remote monitoring, require specific diagnoses in order to be paid. We urge CMS to identify use cases where it would be appropriate to pay for such services for prevention. Some examples may include continuous glucose monitors for patients with obesity who are prediabetic[8] or sleep tracking devices for patients with improper sleep who may be at risk for associated chronic conditions[9]. CMS could also consider leveraging its authority under the Center for Medicare and Medicaid Innovation (CMMI) to establish pilot programs or demonstration projects to incentivize the integration and evaluation of AI technologies into practices, specifically for preventive healthcare services. These pilots could evaluate cost-effectiveness, patient outcomes, and operational efficiencies that could guide broader AI payment reforms.

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[6] Michael Albrecht, Denton Shanks, Tina Shah, Taina Hudson, Jeffrey Thompson, Tanya Filardi, Kelli Wright, Gregory A Ator, Timothy Ryan Smith, Enhancing clinical documentation with ambient artificial intelligence: a quality improvement survey assessing clinician perspectives on work burden, burnout, and job satisfaction, JAMIA Open, Volume 8, Issue 1, February 2025

[7] MedPAC June 2024 Report, Chapter 4. Available here.

[8] Battelino et al, "The use of continuous glucose monitoring in people living with obesity, intermediate hyperglycemia or type 2 diabetes". Diabetes Research and Clinical Practice. May 2025. Available here.

[9] National Heart, Lung, and Blood Institute, "What Are Sleep Deprivation and Deficiency?" National Institutes of Health. Available here.

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Overall, the AOA recommends that the Centers for Medicare & Medicaid Services (CMS) prioritize policy development to improve payment for innovative technologies by:

- **Identifying ways to help practices invest in products that are considered operational or "practice expense" that may improve patient care and enable physicians to spend more time with patients;**
- **Develop a comprehensive approach to payment of "software as a service" under the Medicare physician fee schedule and establish payment for use of such technology in preventive care;**
- **Develop a payment pathway for digital therapeutics; and**
- **Work with Congress in areas where its authority to establish payment is limited.**

Ensuring adequate payment and the ability of practices to invest in new technologies is central to adoption. Developing comprehensive payment reform will ensure that the U.S. healthcare system remains at the cutting edge of implementing innovative tools in patient care, improving outcomes across the country.

Data Exchange

What are ways CMS or partners can help with simplifying clinical quality data responsibilities of providers?

The AOA strongly supports aligning quality reporting across payors. Physicians who participate in MIPS or CMMI alternative payment models must report measures required under the respective programs, and then must comply with separate requirements imposed by plans, which often rely on Healthcare Effectiveness Data and Information Set (HEDIS) measures rather than CMS-developed measures. Additionally, Medicaid managed care plans, Medicare Advantage plans, and commercial market plans often have varying requirements, creating a great amount of reporting complexity and administrative burden. **Automating reporting through reliance on electronic measures, as well as use of consistent individual measures across programs, can help streamline reporting and will ensure that quality measurement is aligned across payers**.

In what ways can the interoperability and quality reporting responsibilities of providers be consolidated so investments can be dually purposed?

FHIR has specifications for quality reporting, and use of these standards for reporting may help automate quality reporting processes. However, current standards are published for trial use, and CMS should work with HL7 to expedite the refinement, testing, and adoption of standards.

Conclusion

Once again, the AOA is pleased to have the opportunity to provide insight on this request for information. We commend CMS and ASTP for seeking public input on policy changes that can support innovation and improve the health technology ecosystem. The AOA looks forward to continuing to work with CMS and ASTP on developing next steps and potential regulations. Should you have any questions regarding our comments or recommendations, please contact John-Michael Villarama, MA, AOA Vice President of Public Policy, at (202) 349-8748 or jvillarama@osteopathic.org

Sincerely,

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