HEALTH INNOVATION ALLIANCE

June 16, 2025

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
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Baltimore, MD 21244

Dr. Thomas Keane, Assistant Secretary for Technology Policy
Assistant Secretary for Technology Policy / Office of the National Coordinator for Health IT
U.S. Department of Health and Human Services
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Re: Request for Information; Health Technology Ecosystem (CMS-0042-NC)

Submitted electronically via regulations.gov

The Health Innovation Alliance (HIA) appreciates the opportunity to comment on the *Health Technology Ecosystem* request for information regarding the market of digital health products for beneficiaries of Medicare, along with the current state of the health technology ecosystem. We believe that this administration has the chance to transform health IT adoption to improve patient and provider experiences, drive efficiencies, and encourage private sector innovation.

HIA is a diverse coalition of patient advocates, healthcare providers, consumer organizations, employers, technology companies, and payers who support the commonsense use of data and technology to improve health outcomes and lower costs.

This administration has the opportunity to make transformational, lasting change in how patients interact with federal health programs and how the Centers for Medicare and Medicaid Services (CMS) manages Medicare. We are excited that CMS is putting a patient-first and technology-forward stance at the core of the mission to improve the system broadly. Crucially, we believe the administration is taking steps in the right direction to adopt and encourage the use of artificial intelligence (AI) where it is safe and makes sense. AI has the potential to address many of health care's most challenging problems, particularly for administrative burden, provider burnout, and workforce shortages. HIA encourages CMS to accelerate the use of AI in health care with resources and incentives across the health ecosystem. Without support and meaningful incentive structures from the government, we run the risk of only the largest or wealthiest health care organizations adopting AI tools. Artificial intelligence should be available throughout the system, including in less resourced sectors like rural and behavioral health care. We look forward to working with CMS to support innovative, technology-forward, and patient-centered reforms. Please see below for our detailed comments.

API Standards (PR-5)
HIA recommends that CMS:

- Promote all APIs that meet the criteria for specific circumstances, rather than choosing one organization's API regime as the "winner".

CMS continues to lean very heavily on one set of application programming interface (API) standards as the agency sets standards for interoperable data systems in the health sphere – HL7 FHIR APIs. The 21st Century Cures Act stipulated that electronic health information (EHI) be accessible via standard APIs – but it did not specify what standards those should be. However, CMS has seemingly favored FHIR APIs across the board as it implements information blocking requirements and interoperability standards. We do not believe it is the government's role to pick winners and losers in the standards space – CMS should promote a variety of API standards that would meet the requirements under the Cures Act. In addition, we remain concerned that CMS is forcing compliance with FHIR APIs that may not be ready for broad implementation. Although it has been nearly a decade since the Cures Act was passed, many FHIR APIs remain incomplete and are not yet ready for industry-wide use.

Patients
Patient Needs (PC-5)
HIA recommends that CMS:

- Incentivize an interoperable data environment where patients do not have to go to great lengths to share or have access to the most necessary, basic personal health information.

We are pleased that CMS Administrator Oz has adopted a patient-focused approach and believe this is a useful lens through which actions to modernize CMS can be taken. At the core of this effort should be encouraging interoperability. In many spheres, such as the electronic health record (EHR) ecosystem, interoperability has long been a key goal, but one that was far off and difficult to achieve. By necessity, there will continue to be incremental steps toward making it easier to share existing data.

We envision a world where data is sharable between payers, providers, and the various stakeholders in between, without special effort. This was the goal of the Cures Act, and while there have been positive steps in the right direction, there remain too many barriers for patients and providers to access needed health and coverage information. Doctors should be able to access all patient-specific health plan information in real time to help guide care during the visit. This includes formulary information and real-time benefit tools (RTBTs) to support prescribing the medication that works best for the patient and is most likely to result in treatment adherence. Without that information, a patient may have difficulty taking a prescription as ordered due to high medication costs, when a lower-cost alternative may have been available.

On the patient side, individuals should be able to opt into enhanced sharing of their information for the purposes of clinical trials and other research. This is a potentially low-lift way to increase the availability real world evidence. Similarly, and consistent with the recommendations from HIA's Interoperability Work Group Report[1], imaging data need to be interoperable. Currently, data sharing from one provider to another often requires the patient to request and transport those

[1] https://health-innovation.org/wp-content/uploads/2023/06/HIAInteroperabilityReport.pdf

files through a physical storage device. CMS should incentivize the use of consistent standards (such as the DICOM standard) for imaging products and clear the way for EHRs and cloud-based storage solutions to make imaging data more easily transferable. Cloud storage options are now ubiquitous in so many sectors, and they should be extended, standardized, and incentivized to relieve this common burden on patients.

Finally, we are perplexed by the CMS focus on patient-facing applications. While we encourage CMS to understand how the private sector is innovating in this area, we discourage the agency from building solutions of their own in this arena. Government technology faces a plethora of issues whenever it is pursued, and this is best left to the private sector. Those issues aside, this may be out of CMS' jurisdiction.

Data Access and Integration (PC-8, PC-12)
HIA recommends that CMS:

- Incentivize private sector solutions that integrate information from a patient's medical record, insurance coverage, and other areas to give the patient and provider clear, easily accessible, and actionable information at the point of care.

Patients and providers need access to a substantial amount of information to make even the most basic care planning decisions. For example, when prescribing a new medication, patients should be able to have their formulary data (specific to their individual plan coverage) available to them and their provider at the point of care. One example of this is real time benefit tools (RTBTs), as mentioned above.

RTBTs aside, there are other data that would be useful to have at the point of care, but remain difficult to access. This includes medical device data that is often not included in an electronic medical record, but would be helpful for a patient to share with their provider to determine whether the current care plan remains appropriate or needs to be adjusted. On the cost side, patients and providers need to be able to easily access specific insurance information, such as whether a patient has met their deductible or out-of-pocket maximum, in order to better guide care decisions. While care decisions should rightly be guided first by clinical indicators and best practices, the number one reason patients are not adherent to their prescribed care regimen (prescriptions in particular) is cost-related pressure. This information should be readily accessible at the point of care so that patients and clinicians do not need to spend significant time or effort locating it in order to determine a care plan that addresses both cost concerns and clinical necessity.

Information Blocking (PC-13)
HIA recommends that CMS:

- Coordinate with OIG to meaningfully enforce information blocking requirements.

The implementation of information blocking requirements and the enforcement of them has not been without its share of issues. While we can speculate about the reasons behind CMS' desire for more submissions of information blocking complaints, we would welcome greater clarity about the agency's underlying motivations. Does CMS wish to develop a clearer picture of the most common areas where information is blocked, in order to better tailor the next steps? Regardless, we believe enforcement through the Office of Inspector General (OIG) has been lackluster. What is the purpose of these requirements if violations go unaddressed? CMS should

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begin enforcing information blocking requirements in earnest, rather than simply collecting more information in the form of complaints without corresponding action.

Digital Identity (PC-14)
HIA recommends that CMS:

- Coordinate with Congress to remove the long-standing prohibition on the use of federal funds for development of a national patient identifier.

CMS sought comments on the adoption of digital identity credentials, potential challenges with them, and what benefits they could have. Identity credentials can be valuable tools to ensure patients get the best care, avoid duplicative or contraindicated care, and promote seamless data transfer. There are numerous digital identifiers in use today, and they are being deployed in a myriad of ways; however, they are often proprietary. Since there has been a lack of federal leadership in this space (and barriers erected in certain instances), a variety of private companies have created their own solutions to verify identity and validate individual patients and their data. The main federal impediment to the adoption of these technologies has been a long-standing prohibition in the Congressional appropriations process that bans the use of federal funds to develop a national patient identifier. This has hamstrung federal agencies like CMS for decades, as they may not take any action to work with the private sector to develop or promote these technologies. We urge CMS to work with Congress and stakeholders to overcome this long-standing barrier and bring the agency's work into the 21st century. Once that impediment is done away with, we would encourage CMS to examine the various solutions that private sector entities have developed to identify patients and explore ways to support and encourage adoption of one or more systems.

Providers (PR-1, PR-2)
HIA recommends that CMS:

- Encourage and incentivize health IT solutions that synthesize patient clinical and insurance coverage data at the point of care.

It is admirable for CMS to encourage providers to leverage digital health products for Medicare patients, but it is important to note that providers cannot control patient behavior. A patient's behavior is not solely dictated by that of their provider, so while a provider can suggest the use of digital tools, there is no guarantee that the patient will utilize them. Moreover, in rural areas, access to these health tools is substandard, so over-relying on the usage of these tools may prove unsuccessful. Though encouraging the use of new technology and thereby streamlining data collection could prove to be successful, its success is not determined by the behavior of the provider but rather that of the patient.

As mentioned previously, both patients and their providers should be able to easily access information about specific plan coverage, deductibles, and out-of-pocket costs. To deliver informed care through accurate and guided decisions, providers should be able to access clinical and coverage data, enabling them to create a realistic care plan. Doctors should be able to access all the individual-specific information for a given patient's health plan in real time at the point of care. It is not realistic to expect clinicians to spend a significant amount of time outside of a given visit reviewing and planning out the patient's course of care in the context of their insurance coverage realities and limitations – clinicians are burdened enough with little time to spare. Rather, facilitating the availability of this information at the point of care sets up a better

patient-provider interaction where all the factors can be considered when laying out a treatment plan.

Digital Identity Credentials (PR-10)
HIA recommends that CMS:

- Encourage development and adoption of a national patient identifier to give providers the tools to provide the best care.

Regarding digital identity credentials, it bears repeating that some sort of unique patient identifier is perhaps even more helpful for clinicians than for patients. These types of identifiers are usually provider-facing, in order to give a more accurate view of all patient information regardless of where care was provided. An identifier would aid the care provider in situations where a patient may have recently moved to a new state or region, or lives in an area straddling several jurisdictions. A good example is regarding opioid use disorder: if a patient lives in Tennessee and was prescribed and dispensed an opioid, and then seeks a similar prescription in Kentucky, a unique patient identifier may be the only link that would make a provider in Kentucky aware that the patient has already received a similar prescription in another jurisdiction.

Information Blocking (PR-13)
HIA recommends that CMS:

- Coordinate with OIG to meaningfully enforce information blocking requirements.

We are pleased that CMS has continued to roll out regulations implementing the information blocking requirements in the Cures Act. However, we believe more could be done to enforce these rules. The subset of providers and facilities that may be resistant to free-flowing information may change their behavior if the information blocking requirements are enforced evenly and aggressively. Only then will the true goal of information blocking requirements be achieved. To date, HHS OIG has not released any public information about enforcement actions, despite receiving almost 1,000 complaints as of May 2024.[2] OIG has the investigatory power, and enforcement mechanisms (such as civil monetary penalties), to enforce information blocking requirements and thereby signal that these rules are not voluntary, but mandatory. The RFI asks how to promote submissions of information blocking complaints to the ASTP/ONC portal, and if increased reporting would advance data exchange. The answer is that without significant enforcement, it is doubtful that there would be meaningful changes in behavior.

Vendors (TD-3, TD-18)
HIA recommends that CMS:

- Standardize data sharing agreements within programs under CMS jurisdiction to provide predictability and rules of the road for participating vendors.
- Promote development and adoption of digital patient identifiers.
- Broaden information blocking requirements to include labs and other vendors.

The health technology ecosystem is evolving at a rapid pace, with new vendors, data providers, and networks arising every day. To ensure patient confidentiality and abide by legal standards,

[2] https://www.healthit.gov/buzz-blog/interoperability/getting-real-about-information-blocking-and-apis

vendors must be subject to standard privacy laws and data use agreements for the actions of the CMS to be sustainable. While standard privacy laws may be in the realm of Congress, CMS can take meaningful action to standardize data use agreements for vendors participating in federal programs like Medicare.

As mentioned previously, a variety of private companies and vendors have created their solutions to be able to verify identity and validate individual patients and their data. However, these private vendor solutions have not been adopted due to impediments set up by long-standing prohibitions in the Congressional appropriations process that ban the use of federal funds to develop a national patient identifier. This impediment stops the CMS from embracing all forms of data and innovative solutions. Overall, CMS should embrace all data as long as it is accurate and verifiable.

Finally, information blocking requirements should be extended to include vendors and other actors that are not currently subject to such requirements. A good example is laboratory vendors – labs are widely used for outsourcing diagnostic testing capabilities, and the industry is expected to grow from $291 billion in 2025 to $466 billion in 2032.[3] CMS has rightly incentivized better testing for various conditions like colorectal cancer through the physician fee schedule, and early testing and identification of disease will continue to be a key part of reducing the chronic disease epidemic. That information can only be used to its greatest potential if it is shared across the health care system – a goal which is only achievable if appropriate incentives and disincentives are in place. Thus, CMS should consider adopting expanded policies, such as information blocking requirements, to labs and other vendors.

Value Based Care (VB-4, VB-11)
HIA recommends that CMS:

- Promote free-flowing data exchange between providers and value-based care entities.

While many of our above recommendations also apply in the value-based care context, we would like to focus on the importance of free-flowing data in this sector. Value based care is completely reliant on tracking outcomes through various patient outcome and provided care metrics. It is difficult enough to establish which metrics should be tracked that would give a clear picture that a course of care is "valuable" or "not valuable" – should care only be valuable if the patient's disease is cured or substantially controlled? Once the appropriate metrics are selected, it is often difficult to collect that data in one place. Value based care often necessitates a broad care team comprising numerous specialists, the primary care team, and various testing and imaging capabilities. If data cannot be shared, or is not appropriately incentivized to be shared, across the care team, then it is very difficult to determine which care is truly "valuable" to the patient.

Conclusion
We thank CMS and ASTP for the opportunity to respond to this RFI, and we look forward to working with you to leverage health IT to create a better health care system.

Sincerely,

[3] https://www.fortunebusinessinsights.com/industry-reports/clinical-laboratory-services-market-100725

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