

June 16, 2025

Via electronic submission at https://www.regulations.gov

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201
Attention: CMS-0042-NC

Thomas Keane, MD, MBA
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C Street SW
Washington, DC 20024

Re: Request for Information; Health Technology Ecosystem; 90 Fed. Reg. 21,034 (May 16, 2025)

Dear Administrator Oz and Dr. Keane:

The Federation of American Hospitals (FAH) is the national representative of more than 1,000 leading tax-paying hospitals and health systems throughout the United States. FAH members provide patients and communities with access to high-quality, affordable care in both urban and rural areas across 46 states, plus Washington, DC and Puerto Rico. Our members include teaching, acute, inpatient rehabilitation, behavioral health, and long-term care hospitals and provide a wide range of inpatient, ambulatory, post-acute, emergency, childrens', and cancer services.

The FAH appreciates the opportunity to provide comments on the Request for Information (RFI) titled *Health Technology Ecosystem*. We are particularly interested in contributing to the discussion around digital health product adoption, data accessibility and exchange, and the reduction of provider burden, drawing upon our experience as healthcare providers that extensively utilize health information technology (health IT). We recognize that effective and responsible adoption of technology can empower patients to make better decisions for their health and well-being. Our comments are structured to align with the key areas outlined

in the RFI, specifically addressing concerns and offering recommendations related to providers, technology vendors, payers, patients, and caregivers.

Digital Health Product Adoption (PR-1)

We acknowledge the potential of digital health products to improve healthcare outcomes and empower patients. However, several obstacles hinder widespread adoption and effective utilization:

- Patient and Provider Awareness and Trust: Many patients lack knowledge about available digital health applications and struggle to identify trustworthy options. Providers, in turn, are often uncertain about recommending suitable solutions, particularly given concerns about patient data security when some apps may be more focused on sales or data acquisition over robust data protection.
- EHR Integration and API Readiness: The industry-wide deployment of patient-facing FHIR (Fast Healthcare Interoperability Resources) APIs remains incomplete, limiting uniform data access even when such functionality is technically enabled by the electronic health record (EHR). Data access for provider-facing applications is an even greater challenge. EHR systems often lack user-friendly FHIR APIs and app integration capabilities, forcing providers to rely on external apps that require manual data entry or to function with inadequate built-in tools. In some cases, the administrative overhead required to support and onboard third-party apps creates additional barriers to wider adoption.

Recommendations for CMS & ASTP/ONC

- Establish a process for reviewing or approving digital health products based on their efficacy, quality, and impact on health outcomes. A trusted third-party certification program could serve as an indicator of reliability and safety for both providers and patients.
- Implement standardized FHIR API requirements and provide clear guidance and implementation support at the provider level. While putting certified vendor products in place is the first step, fully implementing and *maintaining* these APIs as reliable tools requires significant effort by providers. CMS and ASTP/ONC should set specific requirements and milestones for API functionality, coupled with incentives to encourage and sustain adherence.
- Encourage clinicians to disclose any conflicts of interest and clearly communicate a product's purpose, data-sharing practices, access permissions, and associated risks when recommending digital health products to patients.

Innovative Applications for Physician Workflows (PR-2)

EHR integration into clinical workflows remains limited. Technologies like CDS Hooks for launching SMART on FHIR apps are still underdeveloped or underutilized in most EHR platforms. A key issue is that many EHR vendors are reluctant to serve as open platforms, preferring to promote their own proprietary tools as a means of differentiation. Furthermore, the volume and complexity of documentation required for billing and quality measure reporting creates an enormous burden on providers. Data extraction and transmission are complicated by varying approaches to data capture across different EHR systems, a lack of standardized workflows and documentation practices, inconsistent interpretation of quality measures, and varied data ingestion methods by receiving agencies. This fragmented landscape hinders streamlined processes for extracting, transforming, and transmitting data for care improvement and reporting purposes.

Recommendations for CMS & ASTP/ONC

- Ensure that EHR product certification criteria prioritize demonstrated real-world integration capabilities (for example, requiring that CDS Hooks can seamlessly launch SMART on FHIR applications within a clinician's workflow).
- Leverage existing, proven data exchange methods in government programs to reduce provider burden. For instance, promote the use of established standards like the Consolidated Clinical Document Architecture (C-CDA) for exchanging clinical information, rather than introducing entirely new reporting tools, to simplify workflows and documentation.

Data Accessibility (PR-3)

It is critically important — in both urban and rural settings — that *all* data contained in an EHR system be accessible for exchange in a standard format. Outside of the data classes defined by the U.S. Core Data for Interoperability (USCDI) standard, most EHR data are stored in proprietary formats with variable headers and metadata. This lack of standardization increases the complexity of patients' ability to access and share their health information. Additionally, information received from external sources is rarely presented within a clinician's workflow at the right time, meaning important data may be overlooked. Limited access to critical information can negatively impact the quality and coordination of care.

Recommendation for CMS & ASTP/ONC

Prioritize simple access to usable, computable data from the USCDI dataset. A reliable
core of standardized data exchange must be established and functioning consistently
before attention is turned to expanding into other data areas or more complex
interoperability challenges.

FHIR API Support and Utilization (PR-5)

FAH members utilize and support many of the APIs noted in the RFI, particularly where use is required by law or program policy. The extent of API adoption and utilization, however, largely depends on the readiness and capabilities of certified health IT vendors. When there are no clear standards or requirements for certified health IT developers to equip providers with certain API functionalities, providers struggle to identify practical solutions on their own.

Recommendations for CMS & ASTP/ONC

- Develop and enforce clear standards for each type of healthcare API and introduce requirements that certified EHR technology (CEHRT) vendors provide these capabilities to their clients with sufficient lead time for successful implementation. Providers should not be left without vendor support for key interoperability functions.
- Promote payer accountability in the realm of electronic Prior Authorization (ePA) and related APIs. Certification requirements and criteria should not focus solely on provider-side technology; they must also ensure that payers develop and deploy secure, efficient tools that seamlessly integrate with provider systems. Payers should be held to parallel standards so that ePA processes truly reduce burden and delays, rather than shifting the interoperability challenge onto providers alone.

Data Exchange & Interoperability: TEFCA and Beyond (PR-6, PC-10, TD-6, VB-15)

Ensuring seamless data exchange is crucial for a functional health technology ecosystem. We offer the following observations regarding current interoperability initiatives:

- TEFCA's Progress: The Trusted Exchange Framework and Common Agreement (TEFCA) is beginning to advance provider access to health information, particularly by simplifying connections to health information exchange networks and standardizing the agreements between participating entities.
- Limited Impact of HIEs: The impact of health information exchanges (HIEs) on patient care has been modest so far. Many providers still resort to direct communication (phone calls, faxes, or individual portal logins) to obtain records, suggesting that HIE networks are not yet fully meeting providers' needs for timely information at the point of care.
- FHIR Endpoint Directory Redundancy: If TEFCA functions as intended and achieves a nationwide mechanism for query-based exchange, a centralized national provider directory of FHIR endpoints may prove unnecessary or redundant. TEFCA's network-of-networks approach could inherently support discovery of endpoints and exchange participants.
- Public Health Reporting Challenges: Public health reporting remains challenging because of the numerous jurisdiction-specific requirements. Hospitals and health systems

must navigate a patchwork of different state and local public health reporting systems and rules, which complicates compliance and adds burden.

Recommendations for CMS & ASTP/ONC

- Concentrate on making the TEFCA framework fully operational and effective, rather than introducing new or parallel interoperability models. In particular, standardized patient matching and record-locator methods should be developed and mandated under TEFCA to improve the accuracy of nationwide data exchange.
- Provide incentives or regulatory options to encourage providers to participate in TEFCA. For example, CMS could facilitate or reward a hospital's connection to a designated Qualified Health Information Network (QHIN) under TEFCA, accelerating adoption and the flow of key health information across networks.
- Identify and establish consistent vocabulary standards for all data elements in USCDI that currently lack them. We strongly encourage ASTP/ONC to close these vocabulary gaps to ensure that exchanged data is uniformly interpretable and useful to receiving systems.
- Develop a national registry or a federated model for certain types of public health reporting (similar to the approach used for electronic case reporting). Such an infrastructure could streamline reporting for immunizations, lab results, disease surveillance, and other public health data by allowing providers to connect once and meet the requirements of multiple jurisdictions. This would significantly reduce the burden on providers and EHR vendors who today must accommodate a complex web of varying public health reporting mandates.

Reducing Provider Burden: Focus on Clinical Quality Data (PR-7, PR-8, TD-15)

The volume and complexity of documentation required for billing and quality measure reporting creates an enormous burden on providers. Data extraction and transmission for quality reporting are further complicated by the fact that different EHR systems capture the required data elements in varying ways. There is a lack of standardized workflows and documentation practices across healthcare organizations, inconsistent interpretation of quality measures, and varied data ingestion formats required by different quality reporting agencies. Looking ahead, new bulk data export capabilities will necessitate greater standardization in how documentation is captured, how clinical documentation aligns with associated results, and how data are interpreted for submission to registries — potentially involving hundreds of data points for each registry or program.

Recommendations for CMS & ASTP/ONC

• Leverage existing data-sharing standards such as Bulk FHIR and C-CDA to create a more *passive* reporting model for clinical quality data. Instead of requiring manual reporting workflows for each program, enable providers to automatically submit standardized

datasets that can serve multiple reporting needs, thereby reducing duplicative effort for all stakeholders.

- Simplify and streamline clinical quality measurement criteria to enhance the effectiveness
 of Bulk FHIR data exchange. CMS should work to reduce the variation, complexity, and
 redundancy across the numerous quality data collection methods. A more unified and
 straightforward set of measures and reporting formats will make automated data sharing
 more feasible and reliable.
- Prepare CMS' own systems to handle the significantly increased data volumes that will
 come with expanded use of bulk data exports. While a single-source-of-truth model for
 quality data (where data can be reused across programs and sites) offers great benefits, it
 also means CMS and downstream systems must be equipped for substantial data
 processing and analysis on the receiving end.
- Take advantage of existing, proven health IT standards that already capture necessary
 clinical information in structured form. In many cases, the data needed for quality
 measures can be extracted from EHRs via standard APIs or documents, which could
 replace or reduce the need for separate Quality Reporting Document Architecture
 (QRDA) file submissions or labor-intensive chart abstraction processes.
- We also note that the goals of various quality measures to be reported are not transparent
 to providers. Therefore, the FAH recommends early and ongoing stakeholder
 engagement to define reporting elements, processes, and frequencies. Proactive
 collaboration is essential to ensure that reporting requirements meet intended objectives
 without overwhelming providers. Early dialogue and stakeholder review will help ensure
 practicality, alignment with real-world hospital experiences, and optimal patient care
 outcomes.

Digital Identity Credentials: Balancing Security and Access (PR-9, PR-10, TD-3, VB-14)

Wider use of digital identity credentials for patients and providers could greatly facilitate data access and information sharing across different healthcare systems. However, cost and other concerns for vulnerable patients must be addressed. For example, vulnerable patient populations may lack access to, or trust in, these digital technologies. Additionally, integrating external credential service providers (CSPs) into existing, often legacy, health IT systems poses significant technical and workflow challenges.

Recommendations for CMS & ASTP/ONC

• Prioritize the availability and use of high-quality, accurate patient matching and identity verification tools. Accurate patient identity matching is foundational to effective care coordination, data aggregation, and population health management, and it becomes even more critical as data sharing increases.

- Help mitigate the costs and accessibility barriers associated with digital identity
 credentials. For example, provide financial or technical support for implementing secure
 identity solutions and focus on patient education so that individuals understand what a
 digital identity credential is and how to maintain its security and privacy.
- Promote the adoption of trusted digital identity solutions by certifying or formally endorsing specific third-party credential service providers (CSPs) that meet stringent security standards (for example, those meeting NIST Special Publication 800-63-3 Identity Assurance Level 2 and Authenticator Assurance Level 2 guidelines). Clear government endorsement can help foster trust in these solutions among both providers and patients.

Addressing Information Blocking Concerns (PR-12, PR-14, TD-18)

Providers are encountering significant challenges in complying with overlapping federal and state regulations governing health information sharing. Regulations such as HIPAA, the ONC Information Blocking rules, and 42 CFR Part 2 governing certain substance use disorder records often impose conflicting obligations, creating undue burdens and legal uncertainty. Additionally, state laws (such as those in California and Texas requiring delays in releasing test results) further complicate compliance, particularly given the current limitations of robust data segmentation technology necessary for selectively withholding sensitive information.

The FAH strongly emphasizes the necessity and urgency of advancing technology capabilities that support data segmentation. Certified health IT currently lacks sufficient functionality to effectively segment data, especially sensitive information relating to behavioral health, reproductive health, and adolescent health records. Without appropriate data segmentation capabilities, providers face substantial operational hurdles and complexity in ensuring patient confidentiality while responding to information requests and managing APIs. We recommend that ONC prioritize accelerating the development and implementation of standardized data segmentation solutions to meet these critical privacy needs, as previously noted in our communications.

Moreover, providers invest significant resources in managing complex and varied jurisdictional privacy and health information management requirements. We urge ONC to collaborate with the Office for Civil Rights (OCR) and other relevant agencies to develop resources assisting providers in navigating these myriad obligations, thereby alleviating confusion and enhancing clarity.

Data segmentation capabilities could also operationalize privacy protections and prevent harm under the information blocking rules. Many physicians express concerns that immediate sharing of sensitive or life-altering test results via patient portals, without contextual clinical discussion, could cause psychological distress or potential physical harm in sensitive situations such as intimate partner abuse. Technologies must support patient preferences regarding the timing and manner of information sharing, enabling clinicians to responsibly manage sensitive data disclosures.

Recommendations for CMS & ASTP/ONC

- Conduct comprehensive reviews and harmonization of federal and state privacy laws to clarify and eliminate contradictory requirements, helping providers avoid conflicting legal obligations.
- Repeal the provider disincentives included in the *Disincentives for Health Care Providers That Have Committed Information Blocking*" final rule (July 1, 2024). This rule provides that hospitals and providers determined to have engaged in information blocking may face reductions in Medicare payment updates, adjustments to payment rates, lower performance scores, and potential ineligibility for certain incentive programs. The FAH supports ensuring that critical health information is available to patients, clinicians treating those patients, and those with appropriate reasons for having access, among which are payment, care oversight, and research. However, the disincentive structure in this rule is excessive and puts hospitals' stability at risk, especially for small and rural hospitals. Further, the Office of the Inspector General processes for determining whether information blocking has occurred are not sufficiently clear and lack transparency, including the appeals process, thus making providers subject to a rule that seems arbitrary and capricious. Alternatively, at a minimum:
 - Prioritize education and collaborative guidance efforts over punitive measures for information blocking compliance, fostering enhanced understanding and cooperation across provider communities.
 - Clearly define the term "intent" regarding information blocking, ensuring providers have precise guidance to mitigate unfair penalties due to ambiguous regulations.
 - o Revisit and refine penalties associated with information blocking, linking severity directly to the violation's nature, scope, and resultant harm.
- Implement phased approaches for providers to adopt information-sharing best practices, supported by practical guidelines and clear examples provided collaboratively by CMS, ONC, and OIG.
- Leverage ASTP/ONC convening capabilities and resources to accelerate the development and real-world testing of standards-based data segmentation solutions. This includes assessing and potentially refining existing standards such as the HL7 CDA and FHIR Data Segmentation for Privacy Implementation Guides and the HCS Security Label Vocabulary. The FAH recommends funding pilot tests that explicitly evaluate patient outcomes, provider usability, and system efficiency, with transparent public dissemination of these findings. Advancing robust data segmentation functionalities will significantly aid providers in effectively navigating complex regulatory landscapes, safeguarding patient privacy, and ensuring compliance with evolving federal and state mandates.

Stimulating Innovation and Developer Engagement (TD-1, TD-2, TD-4)

The FAH believes that innovation in health IT can be accelerated by expanding the types of data and support that CMS makes available to developers. In particular, developer capabilities would be significantly enhanced if CMS' APIs provided access to a broader array of useful data. For example:

- Claims and Outcomes Data: Real-time Medicare claims data and patient-reported outcome data made accessible via API would allow developers to create tools that help providers and patients track care episodes, costs, and results more effectively.
- Social Determinants of Health (SDOH): Integrating patients' social determinants of health data alongside clinical data would give developers and care teams a more comprehensive understanding of each patient, supporting more holistic and personalized care interventions.
- **Price Transparency Information:** Providing data such as co-payments and deductible status through APIs (in a way that can be shared with patients in apps or patient portals) would enable developers to build features that improve cost transparency and help patients anticipate and manage healthcare expenses. This also could facilitate point-of-service payment collections via integrated tools.
- Additional Data Sources: Incorporating information from sources beyond traditional clinical records for instance, state immunization registries, prescription drug monitoring programs (PDMPs), and social services databases could greatly enrich the data available through initiatives like CMS' Blue Button 2.0. By complementing core clinical data with these sources, developers can enhance care coordination and population health analytics in their applications.

However, we recognize that there are significant challenges to making such innovations feasible. These include fragmented data governance (with data ownership and sharing rules varying by source), inconsistent API implementations across different health IT platforms, and ongoing privacy and security concerns that can restrict data sharing.

Recommendations for CMS & ASTP/ONC

- Incentivize health IT developers to focus on Medicare beneficiary needs by offering targeted grant programs or other incentive programs, and by facilitating strategic partnerships (for example, between startups and provider organizations) to address specific high-priority use cases. Direct support and recognition from CMS can draw more innovators into solving Medicare's unique challenges.
- Establish and consistently enforce robust interoperability standards in the long term. A stable, widely adopted set of standards is critical for sustaining innovation: when developers can rely on uniform data formats and APIs across the industry, they are more likely to invest in building new tools that work at-scale across the healthcare system.

Encourage the development and use of open, standards-based APIs by aligning
government health IT certification criteria and procurement policies with interoperability
goals. CMS and ONC should also support open-source and low-cost technology
solutions where appropriate, offer incentives (such as bonus points or preferential scoring
in programs) for adopting standardized APIs, and sponsor educational outreach to the
healthcare community once new standards are published so that developers and providers
are aware of them and capable of using them.

Enhancing USCDI, Certification Criteria, and Data Standards (TD-7, TD-8, TD-9)

The USCDI standard has advanced data standardization and improved interoperability, but gaps remain in both the scope of data it covers and the timeliness and completeness of data exchange. Notably, USCDI does not address certain critical use cases such as claims management information (for example, claim status or documentation exchange between providers and payers). As a result, providers often still rely on inefficient methods like fax and phone calls to obtain needed claims information, due in part to inconsistent coding practices among payers. Some limitations reflect USCDI's defined scope (it is focused on core clinical data rather than administrative data) and others stem from inconsistent implementation of USCDI across different health IT systems.

We caution that simply adding more data elements to USCDI, while it could increase the standard's utility, also risks introducing complexity and raising the implementation burden on health IT developers and providers. Moreover, without clear technical standards (vocabularies, code sets, formats) associated with each new data class and element, the mere presence of additional data in USCDI would not guarantee that the data are interoperable or useful. Exploring the inclusion of less structured or non-proprietary data formats might improve overall data coverage, but doing so would require sophisticated data processing capabilities and could lead to variability in how information is captured and exchanged.

In parallel, we see opportunities to strengthen health IT certification criteria and related data standards to better support interoperability. Health IT certification should place greater emphasis on the functionality and real-world usability of APIs and data exchange capabilities, as well as on security. The API and data integration layer is fundamental to enabling robust features for end-users; thus, standardization in how data are entered and exchanged (including conventions for data entry, file types for scanned documents, and standardized image formats) is essential for improving the clinician and patient experience.

Recommendations for CMS & ASTP/ONC

Provide clearer and more granular guidance within USCDI to differentiate data collection
and reporting requirements between different care settings. ASTP/ONC should specify
which data elements are most relevant for inpatient hospitals versus ambulatory care
settings, for example. This tailoring of USCDI will promote more accurate and relevant
data capture across diverse healthcare environments, ensuring that each type of provider
is focusing on the data that matter most in their context.

- Identify and promulgate appropriate vocabulary and code standards for all USCDI data elements that currently lack them. Consistency in how each data element is defined and coded (for instance, using a standard terminology for social risk factors or a uniform code set for certain clinical assessments) will make exchanged data far more useful and reliable.
- Ensure that ONC's Health IT Certification Program criteria prioritize critical interoperability features. Certification requirements should emphasize API functionality, data security, and proven real-world usability of data exchange. In particular, certification standards should address the uniformity of the data integration process including establishing standard protocols for entering data into EHRs (to improve consistency), standardized file formats for incorporating external documents or scanned records, and common image formats for medical images. Such standards will help different systems handle data in a more uniform way and enhance the end-user experience.

Endorsing Non-CMS Data Sources and Networks (TD-12)

Outside of CMS-run networks and data exchange frameworks, providers often have the option to join various health information networks or data exchange services. We believe an evidence-based endorsement system for these non-CMS data sources and networks would help providers make informed decisions about which networks best meet their needs. By "endorsement system," we envision a framework where HHS (or another trusted, independent body) evaluates and publishes comparative information about such networks. For instance, useful metrics that could be part of an endorsement program include:

- Network Reliability: Frequency of network or access outages reported.
- Security: Any data breaches or significant security incidents disclosed.
- **Participant Base:** The number and types of participating organizations (indicating the breadth of exchange partners a new participant would have access to).
- **Data Sources Supported:** The variety of EHR platforms and other data sources the network can connect with (demonstrating interoperability with commonly used systems).

By having standardized information on these factors, providers could better assess the value and trustworthiness of different health information networks. We encourage CMS and ASTP/ONC to consider developing such an endorsement or transparency program as a way to spur improvements among network service providers and to guide healthcare organizations toward high-performing networks.

Opportunities with Full EHI Access via APIs (TD-13)

While USCDI provides a core set of data for exchange, it does not capture all of the detailed and nuanced information contained in a patient's complete electronic health information (EHI). Expanding API access to encompass full EHI (beyond the USCDI subset) presents an opportunity to enable more holistic care delivery and powerful real-time analytics. For example, researchers and care coordinators could gain insights from clinical notes, diagnostic images, and other rich data not currently standardized in USCDI, potentially improving decision-making and outcomes.

However, granting full EHI access via APIs also raises considerable technical and privacy challenges. The sheer volume of data in a complete EHR (including unstructured text and large files like imaging studies) can be overwhelming to transmit and process. Additionally, ensuring that sensitive information is appropriately protected — and that data requests are handled in compliance with privacy regulations — becomes more complex when the universe of accessible data greatly expands. We support continued exploration of this idea but urge CMS and ASTP/ONC to proceed cautiously and develop robust safeguards and infrastructure to manage the scale and sensitivity of full EHI if such access is pursued.

Value-Based Care Organizations

Healthcare providers participating in value-based care arrangements (e.g., Alternative Payment Models (APMs), accountable care organizations) face unique challenges and opportunities with respect to health IT. Below we address several specific points raised in the RFI:

Digital Health Adoption (VB-1): Within APMs, the primary obstacles to adopting digital health tools include insufficient funding and unclear standards, especially if initial funding for digital innovation was misallocated due to a lack of well-defined interoperability standards, which has hindered progress. Additionally, the absence of a standardized approach to digital health product reimbursement — evidenced by the proliferation of disparate reimbursement codes for digital services creates confusion and can disincentivize adoption. We see a need for an evidence-based endorsement system to rigorously evaluate digital health products. Such a system would boost confidence among both patients and providers by highlighting products proven to be effective and suitable for integration into value-based care arrangements.

Integrating Themes and Technologies into APM Requirements (VB-2): To better integrate digital health and data-driven care approaches into APMs, more emphasis should be placed on developing accurate, real-time patient attribution methodologies that fairly assign responsibility for patient outcomes. Providers in value-based arrangements need to know as soon as possible which patients they are accountable for, and attribution rules should accurately reflect providers' contributions to a patient's care. There is also a critical need for a common, affordable risk stratification tool or methodology that is accessible to all providers, regardless of their size or resources. Such a tool would establish a consistent baseline for identifying high-risk patients across diverse geographic regions and patient populations, helping level the playing field and guiding targeted interventions in a standardized way.

Essential Health IT Capabilities for Value-Based Care (VB-3): Seamless and timely data exchange is one of the most essential health IT capabilities for success in value-based care. Providers must be able to obtain data from all relevant sources — including payers — without being limited by the delays of claims adjudication. Clinical decision-making often cannot wait for a claim to be processed. Real-time or near-real-time access to data (for example, notifications when a patient has an encounter at another facility or fills a prescription) is crucial. Additionally, effective and secure patient communication tools are paramount: user-friendly patient applications, robust patient portals with bidirectional messaging, and two-way data feeds between payers and providers (to exchange information on care gaps, authorizations, or care management activities) are all vital for coordinated, data-driven decision-making.

Optimizing Digital Health Products in APMs (VB-8): Electronic patient event notifications (e.g., alerts that a patient has been admitted to or discharged from a hospital) are intended to improve care coordination, but their current implementation often falls short. The absence of a consistent framework for these notifications results in fragmented and often excessive alerts, making them more of a nuisance than a help to clinicians. We recommend that policies focus on establishing clear standards for event notification content and transmission so that these alerts can be seamlessly integrated into clinical workflows. With standardized, high-value notifications (for example, including pertinent information and sent only to the appropriate provider at the right time), APM participants can use them to ensure timely follow-up and improved care transitions, rather than being tempted to ignore an overwhelming flood of alerts.

Technology Requirements for APM Organizations (VB-9): To promote fairness and consistency, technology requirements should be standardized across both APM and non-APM healthcare organizations. A unified approach to quality reporting, interoperability, and other key functionalities ensures that all providers operate under the same expectations and technical standards. This fosters collaboration and smooth data exchange throughout the healthcare ecosystem and prevents the creation of two divergent tiers of health IT adoption.

Payers

TEFCA Policy and Technical Limitations (PA-1): We have concerns that payers, as participants in health information networks (for example, under TEFCA), might use the data they obtain for purposes that are unintended or not clearly disclosed to patients — such as mining clinical data to support coverage denials or payment decisions. It is vital to ensure strong policies and oversight so that patients understand exactly how their data will be used once shared. In particular, patients should be made aware of the distinction between providing *consent* for data sharing and the *authorization* that covered entities have for data use; data that moves outside of the traditional HIPAA-covered entity environment may be used in ways patients do not expect or intend. We encourage CMS and ONC to monitor payer behavior in these data exchange initiatives and consider guardrails that prevent misuse of clinical data for adverse determinations.

Encouraging Payers to Accept Digital Identity Credentials (PA-3): To facilitate the acceptance of digital identity credentials by payers, CMS could establish expectations or incentives and promote broad education on the value of these credentials. For example, CMS might require or

strongly encourage payers to support a common set of digital identity standards (allowing patients to use one trusted digital identity across multiple health plans). Wider use of digital identity credentials in the payer domain could provide streamlined access for patients to their insurance information (such as retrieving plan details or calculating real-time co-pays) and also facilitate secure data sharing between payers and providers. Education for both beneficiaries and payer organizations will be important so that these stakeholders understand the security and convenience benefits of digital identities.

Additional Considerations

Medicare Promoting Interoperability Program – SAFER Guides Assessment: While we recognize and support CMS' focus on EHR safety and effectiveness, we urge reconsideration of the current requirement for a strict "yes" attestation to completing the SAFER Guides in the Medicare Promoting Interoperability Program. The SAFER (Safety Assurance Factors for EHR Resilience) Guides are an important tool, but the ONC Health IT Certification Program already encompasses many established EHR safety practices and assurances. Rather than making completion of the SAFER Guides a mandatory attestation (which could inadvertently penalize well-meaning providers due to technicalities in how they review and document the Guides), CMS might consider replacing that requirement with a positive incentive for SAFER Guide completion or exploring alternative methods to promote EHR safety. This approach would encourage hospitals to engage with the SAFER Guides toolkit in a more meaningful way, rather than treating it as a checkbox, and it would continue to drive safety improvements without adding undue burden.

Innovation within Program Objectives: We encourage CMS to place greater emphasis on fostering innovation in the Promoting Interoperability Program's objectives. One way to do this is by reintroducing a "menu" of optional measures, as was available in earlier iterations of the program. This would allow eligible hospitals to select certain innovative measures that align with their strategic goals or areas of need and receive credit for those activities. Such an approach gives providers flexibility to try new technologies or workflows (such as advanced use of predictive analytics, patient engagement tools, or novel interoperability use cases) and demonstrate their value. We are also interested in understanding how CMS plans to incorporate Electronic Prior Authorization into the Promoting Interoperability scoring methodology in the future, since that will be a significant new workflow with implications for EHR functionality and provider operations.

Public Health Data Exchange and Reporting: The FAH strongly supports CMS' efforts to centralize and streamline public health data exchange and reporting. However, we urge a thoughtful, measured approach to implementing new public health reporting requirements to prevent undue provider burden and unintended compromise to data quality. Specifically, we recommend:

• <u>Comprehensive Federal and State Reporting Alignment</u>: CMS should collaborate proactively with state public health agencies and the CDC to align federal and state reporting standards clearly and consistently, preventing confusion and redundant or conflicting obligations.

- Focus on Data Quality and Interoperability Standards: Efforts should prioritize enhancing the quality and usability of existing data streams rather than merely expanding the scope of data submissions, avoiding creation of additional disconnected data silos.
- <u>Promote HL7 FHIR Integration and System Modernization</u>: Advocate for an interoperable framework leveraging modern standards like HL7 FHIR, promoting consistency and ease of data exchange between providers and public health authorities.
- Enhanced Collaboration and Standardization: Strengthen cooperation between ASTP/ONC and CMS to uniformly apply certification and reporting standards across jurisdictions, ensuring streamlined, high-quality data submissions.
- <u>Maintain Standards During Public Health Emergencies</u>: Uphold established standards consistently during crises to avoid disruptive, ad hoc changes. Strong, flexible standards already in place facilitate more effective and timely crisis response.

We believe the above recommendations will significantly contribute to the development of a more effective, safe, and interoperable health technology ecosystem. The FAH appreciates the opportunity to submit these comments, and we stand ready to work with CMS and ASTP/ONC on these critical issues. If you have any questions or if we can assist CMS as it considers these recommendations, please contact me or a member of my staff at (202) 624-1500.

Malmatt