June 13, 2025

The Honorable Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

The Honorable Thomas Keane, MD
Assistant Secretary for Technology Policy;
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
330 C St. SW, 7th Floor
Washington, D.C. 20024

Submitted electronically via regulations.gov

RE: CMS-0042-NC; Request for Information; Health Technology Ecosystem

Dear Administrator Oz and National Coordinator Keane:

On behalf of the American Academy of Family Physicians (AAFP), which represents 128,300 physicians and medical students nationally, I write in response to the Department of Health and Human Services' (HHS) Centers for Medicare and Medicaid Services (CMS) and the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology's (ASTP/ONC) request for information (RFI) on the current status and opportunities for the advancement of the health technology ecosystem. The AAFP supports the goals outlined in this RFI, and we appreciate the agencies undertaking this collective effort to learn more about how the effective and responsible adoption of technology can empower patients and physicians to work together to make the best decisions possible for each individual's health and well-being. We believe health information technology (IT) and the health care data ecosystem must facilitate efficient information sharing without undue financial or administrative burden on patients, physicians, or physician practices, and we are grateful for the opportunity to share our recommendations with the agencies.

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Section: Patients and Caregivers; Subsection: Patient Needs

PC–5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?

The AAFP supports the Administration's efforts to increase patients' knowledge of and interest in digital health products and to utilize technology innovations in the health care sector to foster transparency of critical health care data for patients, physicians, and payers. **We believe the following efforts will encourage patient and caregiver interest in digital health products: increasing the transparency of cost, pricing, and utilization of health care data; prioritizing products' ease of use and alignment with patient/caregiver digital literacy levels; strengthening and standardizing interoperability standards of data systems and information sharing for patients, physicians, and payers; empowering patients to be informed decision-makers through education; and enabling patients to own their health care data**. The AAFP believes the safety and privacy of patients' health care information and data must be preserved and that all entities in the health care ecosystem responsible for safeguarding patient data must be subject to the highest standards of protection and security. We understand that a confidential relationship between physician and patient is essential for the free flow of information necessary for sound medical care, and we believe that state and federal legislators should seek a greater degree of standardization regarding the privacy of medical information.

PC–6. What features are most important to make digital health products accessible and easy to use for Medicare beneficiaries and caregivers, particularly those with limited prior experience using digital tools and services?

Before identifying the most important individual features for making digital health products accessible and easy for Medicare patients and caregivers to use, the AAFP believes it's important to begin by asking each patient their level of interest and specific motivations for using digital health products. Patients' preferences and care goals need to be prioritized before introducing new digital health products to their care plan. Ideally, a digital health navigator would be available to conduct a digital health literacy assessment and assist the Medicare patient or caregiver with learning about any new digital health product. The AAFP understands that as a patient's health literacy increases, so does their engagement and ability to self-manage their care. Because of this, **understanding a patient's level of digital health literacy and having**

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educational materials available in a patient's native language are key to increasing accessibility to digital health products.

Additionally, there are logistical challenges that limit accessibility for Medicare patients and caregivers, including a lack of broadband internet access in large parts of the country and lack of access to smartphones.[i] The lack of modern broadband infrastructure has proven to be a primary barrier to equitable telehealth and digital health access for rural Americans, who are 10 times more likely to lack broadband access than their urban counterparts, leading to fewer audio/video visits. The AAFP therefore recommends that CMS work with Congress to pass legislation codifying the ability for CMS to permanently cover and pay for audio-only telehealth services to bridge gaps in access to care. We also encourage CMS work with Congress to ensure that patients in need can access end-user devices, such as tablets, to connect to digital health tools and invest in training and assistance so patients can use them with confidence.

Section: Providers; Subsection: Digital Health Apps

PR–1. 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?

The AAFP believes all patients and physician practices should have broadband access to support the delivery of telehealth and telemedicine services, as well as the increasing availability of digital health products. As these services continue to expand, we encourage CMS and ASTP/ONC to support rural and underserved communities' access to broadband to ensure patients nationwide can acquire and use approved digital health products. To support physicians' adoption and use of digital health products in a broad variety of communities and practice settings nationwide, the AAFP recommends CMS and ASTP/ONC continue to facilitate easy patient access to approved digital health products through coverage and payment mechanisms. Family physicians want to offer their patients the opportunity to improve their health through the use of approved digital health products, but those products must be consistently accessible and affordable for patients in order for there to be improved outcomes long-term. One example of this is making (or continuing to make) the purchase of approved digital health products an eligible expense for flexible spending accounts (FSAs). Additionally, the AAFP supports payment for digital health navigator services being made available through Medicare to facilitate digital

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health literacy assessments and provide assistance to patients and caregivers learning about any new digital health product.

The AAFP recommends CMS and ASTP/ONC work together to develop a suite of educational resources designed specifically for small and independent physician practices, many of which are in rural and underserved communities, to teach them about newly approved and available digital health products, including AI tools. Family physicians want and need to know about new digital health products that could help their patients, but they are often so overburdened, they do not have time to seek out these tools. Instead, it would be ideal if physicians could rely on CMS and ASTP/ONC for newly approved digital health product alerts and related educational resources. For optimal clinician usability, developed resources should be concise and actionable, outlining the insights and actions practices would need to take to utilize a new digital health product.

PR-1a. What are the current obstacles?

Locating and accessing the data required to enable success in a value-based care (VBC) setting is currently a large obstacle for primary care physicians. Given the struggle to obtain key data, it can be difficult to envision incorporating data from a new digital health product into a practice's clinical workflow. The AAFP believes clinically relevant and actionable patient information should be readily available in a "timely, accurate, secure, and efficient manner that does not place unnecessary administrative or financial burdens on primary care practices." We encourage CMS and ASTP/ONC to pursue every avenue for improving the health care system's ability to securely share health data in real time.

Variability in payer eligibility, coverage, and procurement requirements, including prior authorizations, acts as a significant barrier to physicians being able to leverage approved digital health products. We believe it can be difficult to influence physicians' interest, adoption, and use of digital health products when they are struggling to understand which existing tools are covered by a given payer. As an example, the AAFP has heard from members that it can be challenging to receive timely approvals for continuous glucose monitoring (CGM) devices. In some time-sensitive situations, members report it can be significantly easier for physicians to do a Professional CGM trial – with the practice providing the device and patient or practice purchasing a disposable sensor – rather than fight to receive authorization for a personal CGM

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device. This "workaround" allows the physician to obtain trial data to inform care or gather the evidence-base for the patient need without having to engage in a prolonged back-and-forth with a payer. We believe these types of obstacles directly hinder CMS and ASTP/ONC's ability to encourage physicians to use new digital health products, because overburdened, frustrated physicians are not going to have time or bandwidth to learn about new digital health tools. To encourage physicians to leverage digital health products, the AAFP recommends CMS and ASTP/ONC prioritize streamlining requirements across payers to reduce physician administrative burden and increase their eased adoption of new products.

Separately, many mobile health applications are above the recommended reading level for patient materials, and many are not available in other languages. To address this obstacle and ensure all patients can access approved digital health products, the AAFP recommends CMS and ASTP/ONC support policies that hold digital health companies responsible for ensuring their products serve as many patients as possible, including through developing patient-facing FAQs and how-to guides written at the average American's 8th grade reading skill level.[ii] We also recommend the agencies support programs that educate patients on digital health technologies and expand the distribution of approved digital health products in rural and underserved communities.

Ensuring primary care physicians, their care teams, and their patients are equipped with all needed health data at the time of care and in a useable format will require the organized efforts of all stakeholders, including purchasers, public and private payers, policymakers, physicians and associated organizations, and data and health IT vendors. We urge CMS and ASTP/ONC to convene these stakeholders and further establish consensus-based information sharing standards that work for patients and physicians.

PR-1b. What information should providers share with patients when using digital products in the provision of their care?

Family physicians prefer to share with their patients how a digital product will be used in the course of their care. The information needs of physicians require that vendors of digital products provide clear transparency around any artificial intelligence (AI) or machine-learning algorithms employed by an approved digital health product, as well as information on any limitations of the product for its intended use. The AAFP understands that explainability is the

currency of trust, so it is crucial for digital product vendors to provide details to physician practices regarding what data a model was trained on and how the model learns from newly input data, for example.

Digital products that handle protected health information should include guidance documentation that details what specific information is going to be collected, stored (if applicable), and transmitted or exchanged by the product, including information on any patient-facing options for sharing and exchange made available via the product. Such information transparency by digital product vendors is critically necessary to enable physicians' ability to share any necessary details with the patient about the digital health product being used. When patients and physicians are able to understand and talk through how a digital health product works and is being used in a care setting, trust is built, which leads to better patient outcomes long-term.

PR–2. 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?

A primary obstacle to the development of useful and effective applications is often the absence or belated inclusion of physicians, including primary care physicians, in the design, development, and real-world testing of applications. There's a critical need for innovative applications that are intuitive, easily incorporated into existing clinical workflows, supportive of cognitive processing and medical decision making, and transparent regarding any algorithms used and health information being accessed.

Insufficient primary care payment means practices typically operate on razor-thin margins with limited ability to invest in IT infrastructure. This challenge is exacerbated for small clinics, both urban and rural, who lack the financial resources to have a full-time IT employee on staff. Instead, a small practice might hire an IT contractor on a part-time basis, where the contractor would be on-site at the practice only a few days a month, if at all. This lack of resources leads to many physician practices being unable to hire people with the right skillset or technical knowledge, which then causes exploring new technology and applications – let alone operationalizing new processes – to feel even more burdensome and inaccessible. The AAFP encourages CMS and ASTP/ONC to consider offering financial assistance and educational

resources to small, independently owned physician practices that want to expand their health IT processes.

The AAFP is glad to see the advancements being made by Health Level Seven (HL7) to decrease burdens associated with documentation requirements and prior authorization processes – including leveraging HL7 use cases of Coverage Requirements Discovery (CRD), Documentation Templates and Rules (DTR), and Prior Authorization Support (PAS) – along with an upcoming requirement within the CMS-0057-F Prior Authorization and Interoperability Final Rule for payers to utilize several much-needed application programming interfaces (APIs). The time-consuming prior authorization processes, which vary across payers and often require manual tasks, burden family physicians and their practice staff; divert valuable resources away from direct patient care; and lead to adverse health outcomes for patients. As such, family physicians are eagerly awaiting the availability of these newly required APIs, and the AAFP appreciates CMS and ASTP/ONC's leadership and collaborative efforts making this possible.

PR–3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (for example, scanned documents, faxed records, lab results, free text notes, structured data fields)? Please address all of the following:

- *Current challenges in accessing different data formats.*
- *Impact on patient care quality.*
- *Technical barriers to full data accessibility.*
- *Cost or privacy implications of making all data formats interoperable.*
- *Priority level compared to other interoperability needs*.

The AAFP strongly believes that it is critically important for nationwide health care delivery and interoperability that all data in an EHR system be accessible for exchange, regardless of storage format. Thankfully, solutions and capabilities required to democratize data access do exist. Technologies capable of receiving scanned documents, faxed records, lab results, free text notes, etc., have long existed. The ability to convert that information into structured data fields within a structured document that is leverageable within an EHR (and for exchange) has existed for many years. Qualified health information networks (QHINS), health information exchanges,

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health data utilities, and a host of data exchange solutions with varied costs and capabilities have also emerged on the scene to support structured data exchange and interoperability between exchange partners of varying capabilities. While these capabilities have long existed, it is deeply unfortunate that they still are not readily available across care settings, rural and urban alike.

Cost and technical barriers to full data accessibility remain prevalent. Independent physician practices still struggle with getting access to hospital admission and discharge data for their patients if staff privileges are not held at hospitals where care is received. This is improving with the emergence of EHR vendors making community physician/provider access available for EHR data on shared patients. However, health systems' privacy and/or privileging policies can also prevent clinicians from gaining access to needed data on their patients in some cases. The AAFP continues to urge CMS and ASTP/ONC to monitor whether the disincentives finalized in the June 2024 final rule on information blocking disincentives are succeeding in sufficiently deterring information blocking by hospitals. Other penalties for hospital noncompliance of federal regulations have in the past had to be strengthened to more effectively outweigh the competitive advantage of noncompliant behavior.

In caring for patients, whether across different settings within the same health system or across multiple health systems, AAFP members share that it can be extremely challenging to access patient and payer data – even when they know the data exists and where it's located. In some instances, employed family physicians or residents may not have access to the same level of patient data in one branch of a health system as in another location. EHR vendors often charge health systems for upgrades on a per-location basis, so useful, time-sensitive data may be in a patient's record but inaccessible at a given location. **The AAFP encourages CMS and ASTP/ONC to consider what regulatory authority they have to require EHR vendors to make patient data available system-wide, regardless of an individual practice location's ability to pay for a technology upgrade**.

Data limitations are rarely the central obstacle to achieving a robust information-sharing ecosystem that enables and supports primary care's success. Rather, the greatest roadblocks arise when organizations prioritize business interests over the needs of patients, primary care physicians, and their care teams, and instead make decisions without fully considering the

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impact on the information sharing environment. **The AAFP recommends prioritizing broad stakeholder and policy support for structured and interoperable data, regardless of data storage format (scanned documents, faxed records, lab results, free text notes, structured data, etc.) for those essential data types described under section VB-4 of this RFI, below, which are required to enable and support primary care success, particularly within a value-based care ecosystem**.

The AAFP believes the following types of data are essential, especially in terms of enabling value-based care success:

- Admission, discharge, and transfer notifications;
- Referral feedback and closure;
- Lab and imaging results;
- Medication fill notifications;
- Accurate and timely patient lists;
- Comprehensive patient demographic information and health status (risk level or score);
- Timely and frequent contractual performance feedback; and
- Cost and quality information on network referral options.

PR–4. What changes or improvements to standards or policies might be needed for patients' third-party digital products to have access to administrative workflows, such as auto-populating intake forms, viewing provider information and schedules, and making and modifying an appointment?

The AAFP supports efforts to make health information more accessible and actionable for patients, such as by enabling patients to access their health information through third party applications that they can download to a smartphone or similar device. However, we remain particularly concerned about the privacy, security, use, and transfer of patient and consumer health data in the ecosystem outside of HIPAA, where it is largely unprotected by federal laws or regulations. The AAFP believes federal legislation is necessary to achieve a greater degree of data standardization and adherence to agreed-upon principles related to the privacy of health data, but we also strongly support the agencies taking actions within their authority to strengthen patient data protections.

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Though current HIPAA regulations are robust, privacy and security protections are limited to covered entities, such as physician practices, and their business associates through business associate agreements (BAAs). This framework places an undue burden on practices to ensure compliance across multiple business associates via individual agreements, requiring staff time and financial resources many practices do not have to spare. As health care continues to evolve and the proliferation of digital health technologies increases, the number of entities interacting with electronic protected health information (ePHI) has grown exponentially, causing the traditional BAA mechanism to become increasingly cumbersome and inadequate in managing the comprehensive privacy and security of ePHI. Many covered entities, particularly small practices, lack the expertise to manage the cybersecurity practices of their business associates. We recommend the agencies consider how best to enforce accountability for business associates, rather than shifting this responsibility to practices.

Additionally, the AAFP encourages CMS and ASTP/ONC to examine the practical limitations of a covered entity's control over certain technical safeguards. For instance, many physician practices rely on vendors for IT updates and protections to firmware and anti-malware. Given how few physician practices can afford to have full technical infrastructure and expertise in-house, we recommend the Department clarify that health IT vendors bear primary responsibility for ensuring timely and effective technical and security updates.

Section: Providers; Subsection: Data Exchange

PR–6. Is TEFCA currently helping to advance provider access to health information? Please provide specific examples. What changes would you suggest? What other options are available outside of TEFCA? Are there redundant standards, protocols or channels or both that could be consolidated?

The AAFP recognizes TEFCA as a national initiative intended to standardize and expand health information exchange. In our call-to-action brief, Information Sharing in Value-Based Payment Models for Primary Care, we acknowledge TEFCA as a step towards establishing a 'universal floor for interoperability'. However, the impact of TEFCA is yet to be determined, with many primary care physicians skeptical of these efforts. This is due in part to the lackluster results of past reforms, which generally increased administrative burden and had an underwhelming impact on access to essential and usable data.

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Feedback from our members has been that TEFCA's focus on clinical data exchange for point-of-care needs misses crucial elements, such as payer-generated attribution lists or quality/performance measurement reporting. Additionally, the payer landscape varies significantly across markets, often making regional information exchange more effective in addressing essential payer-generated data elements.

It's also important to note that there are several emerging health information sources that are poorly connected to existing health infrastructure or lack standardization**.** As direct-to-consumer health care companies proliferate, more patient health data are being isolated from the existing information sharing environment. Additionally, more patient data are being generated by consumer-facing applications and medical devices that are inadequately equipped to engage in secure information sharing. Health-related social needs data are increasingly being used, but widely accepted standards for how this information is represented within the EHR are just emerging and are not widely adopted.

PR–7. What strategies can CMS implement to support providers in making high-quality, timely, and comprehensive healthcare data available for interoperability in the digital product ecosystem? How can the burden of increasing data availability and sharing be mitigated for providers? Are there ways that workflows or metrics that providers are already motivated to optimize for that could be reused for, or combined with, efforts needed to support interoperability?

To best support physicians and their care teams in making high-quality, timely, and comprehensive health care data available for interoperability in the digital product ecosystem, the AAFP recommends the following strategies, which long-term will allow for more effective care coordination and ultimately improve patient outcomes.

- Continue and accelerate the USCDI process. We believe ASTP/ONC should continue to advance USCDI to expand the breadth and depth of highly structured clinical and non-clinical data to support deep integration across EHR systems.
- Develop and implement payment models that reward multifaceted interoperability.
- Provide financial and technical assistance, especially for independent and small practices (similar to HITECH efforts).

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- Provide financial and technical support for regional HIE and HDU networks.
- Encourage interoperability and external data integration directly in clinical and administrative workflows.
- Promote FHIR standards to encourage data standardization and consistency.

PR–8. What are ways CMS or partners can help with simplifying clinical quality data responsibilities of providers?

The AAFP recommends CMS work to reduce variability among insurers and plans. Family physician practices typically work with seven to 10 different payers, with about half working with more than a dozen. Variability with discoverability (what, when, and how data is to be submitted), data submission method(s), data definitions, and overall measures used lead to a significant level of administrative burden on practices. Even if each insurer streamlined these processes, if it isn't standardized among all insurers, serious administrative burden remains at the practice level.

PR–8a. What would be the benefits and downsides of using Bulk FHIR data exports from EHRs to CMS to simplify clinical quality data submissions? Can CMS reduce the burden on providers by performing quality metrics calculations leveraging Bulk FHIR data exports?

While Bulk FHIR data exports would likely decrease the technical burdens of transmitting the clinical quality data, it would not address the other variabilities that are leading to the greatest burden, such as disparate data definitions and the overall measures used across insurers. The AAFP does not oppose CMS using Bulk FHIR data exports in this way, but we urge the agency to also address other variabilities that are causing family physicians even more burden than that of clinical quality data submissions.

PR–8b. In what ways can the interoperability and quality reporting responsibilities of providers be consolidated so investments can be dually purposed?

Again, the AAFP recommends CMS work to reduce variability among insurers and plans. This, alongside efforts to encourage participation in and appropriate payment for value-based care models, would help maximize agency investment while driving technological advancements in health care.

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PR–8c. Are there requirements CMS should consider for data registries to support digital quality measurement in a more efficient manner? Are there requirements CMS should consider for data registries that would support access to real-time quality data for healthcare providers to inform clinical care in addition to simplifying reporting processes?

While pulling clinical quality data from a data registry would decrease the administrative burden for practices that are using a registry, this of course only works if the clinical data has been submitted to the registry and the registry is easily accessible. As we have stated throughout this letter, significant administrative burden will remain on practices if standard definitions and measures are not implemented. One potential advantage of a registry, particularly with a specialty-supported registry, is that it will focus on the quality measures most applicable to the specialty and needed quality improvement. In such situations, insurers could simply accept the measures used by the registry and easily standardize across insurers.

Section: Providers; Subsection: Digital Identity

PR–9. How might CMS encourage providers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins that need to be tracked for each provider relationship?

The AAFP supports any data collection, including identity credentials, complying with the principles laid out in our Data Stewardship Policy. Additionally, the value of such a common digital identity would follow Metcalfe's Law, which states that the value of a network is proportional to the square of the number of members. Therefore, the more entities that would accept the digital identity the more likely it is to be adopted by patients and physicians. Finally, any process implemented to use digital identity credentials must not increase physician burden; the digital identity must integrate seamlessly with the technologies that already support easier logins by physicians.

PR–9a. What would providers need help with to accelerate the transition to a single set of trusted digital identity credentials for the patient to keep track of, instead of one for each provider?

The AAFP recommends CMS and ASTP/ONC incorporate the following ideas into their strategy to accelerate the transition to a single set of trusted digital identity credentials:

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- Educational resources for both patients and physicians addressing how patients can get and use digital identity credentials;
- Utilizing third-party validation to help demonstrate to patients and physicians that the digital identity provider is safe and trustworthy;
- Publication of clear guidance explaining how the digital identity provider is assuming the liability of protecting the digital identity credentials from fraud, identity theft, and other cybersecurity threats; and
- Having a similar, nationally recognized digital identity credentialing system for physicians and other health care workers.

PR–9b. How might CMS balance patient privacy with convenience and access to digital health products and services that may lead to significant improvements in health?

To help achieve the goal of balancing patient privacy with convenience and access to digital health products, the AAFP recommends CMS: 1) extend HIPAA regulations to digital identity providers; and 2) require digital identity providers to publish clear, straightforward data use policies – not written above an eighth grade reading level – that are readily available online to patients and the public.

PR–10. Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800–63–3 IAL2/AAL2 CSPs):

PR–10a. What are the challenges and benefits for providers?

Most clinicians will be dependent on health IT vendors to provide the capabilities around digital identity credentials, and some health IT vendors may need specific incentives or penalties implemented by the federal government before opting to provide such capabilities. If such incentives are required, there is concern that the vendor would provide the bare minimum required instead of a robust, user-centered design that is needed. This would lead to a poor user experience, less adoption of these credentials, and more administrative burden for physicians and their care teams. **If CMS and ASTP/ONC choose to pursue regulation in this area, the AAFP encourages the agencies to include physician and clinician perspectives from the outset of the project. End-users can help ensure any digital identity credential system**

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developed will center patients and physicians, as well as prioritize integration with existing clinical workflows to mitigate additional administrative burden.

PR–10d. What impact would mandatory credentials have on a nationwide provider directory?

The AAFP believes having a single place to maintain a digital identity and accompanying physician-specific data would be very helpful to family physicians, and we appreciate CMS and ASTP/ONC's thoughtful consideration of how these topics potentially interact. **The AAFP encourages the agencies to not mandate anything before a properly developed system featuring user-centered design has been established; to do otherwise would most likely result in an increase in administrative burden**. Instead, we recommend only mandating after a significant number of physicians have voluntarily entered their information. This will ensure the system functions well for its users and will drive design that provides value to physicians and other third parties.

PR–10e. How could digital identity implementation improve provider data flow?

If the digital identity is for the physician/practice and is accepted widely, implementation could improve flows of information immediately. As many family physicians work with at least seven to 10 insurers at any given time, having a single login process that would allow automatic login during a specific period of time would significantly improve physicians' workflows. That said, it is critical to continue to move forward with standardized bidirectional API-based exchange between physician EHRs and insurer information systems. We appreciate CMS' leadership in this area and look forward to further progress in the coming years.

PR–10f. Would combining FHIR addresses and identity improve data flow?

To ease the digital identity implementation and support data security, the AAFP recommends that the data stored by the digital identity provider should be only the minimum data necessary to provide the service. Additionally, data like FHIR addresses, physical addresses, and contact information will likely change many times over the course of a physician's life, whereas the digital identity should not change, unless one must change identity providers. For these reasons, the AAFP supports separation between FHIR addresses and digital identity credentials. With that said, we suggest the agencies consider if the digital identity could be used to assert

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the authenticity of the FHIR addresses, given that those addresses could then be maintained in a national provider directory.

Section: Providers; Subsection: Information Blocking

PR-12. Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of electronic health information (EHI) and to promote market competition?

The AAFP has long supported the agencies' efforts to advance interoperability of health IT, including through ASTP/ONC's development of information blocking regulations. Interoperability is essential for ensuring family physicians have access to meaningful, actionable data at the point of care, which in turn enables them to provide high-quality, patient-centered care across the lifespan. A truly interoperable health data ecosystem will reduce administrative tasks for physicians, improve patients' access to their health data, and support HHS' goal of transitioning the health system to value-based care.

The AAFP remains largely supportive of the information blocking exceptions and conditions within the exceptions as written, and we don't believe they need to be significantly revised. However, we continue to urge ASTP/ONC to simplify, clarify, and align as many requirements and definitions within the information blocking regulations as possible. Disparate definitions for the same terms across different health IT and other regulations can create confusion and add to the burden for physician practices working to ensure they are in compliance. **We urge HHS to collaborate with its counterparts across the agencies to align terms and definitions used in rulemaking with other health and IT regulations**.

Additionally, as we have repeatedly shared with ASTP/ONC, physicians continue to report confusion with provisions of the information blocking regulations, including on the appropriate application and documentation of information blocking exceptions, what is considered an "unreasonable practice" when evaluating for information blocking, and the parameters governing "actual knowledge" as an expected enforcement priority. Family physicians want and need best practices and implementation guides that they can reference as they strive to understand and comply with these regulations.

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We continue to urge ASTP/ONC to work with CMS and HHS to develop a suite of educational resources designed specifically for small and independent physician practices, many of which are still unaware or underinformed of information blocking requirements. For optimal clinician usability, resources should be concise and actionable, outlining the insights, steps, and actions practices need to take to ensure they are fulfilling information blocking requirements. We strongly encourage ASTP/ONC and CMS to engage physicians in small and independent practices in the resource development process to ensure their educational and operational needs are fully met. Providing physicians with the resources needed to fully understand the requirements will allow them to share information most appropriately and effectively, which will support a strong health technology ecosystem.

PR-13. For any category of healthcare provider (as defined in 42 U.S.C. 300jj(3)), without a current information blocking disincentive established by CMS, what would be the most effective disincentive for that category of provider?

The AAFP agrees with CMS and ASTP/ONC that it is important for disincentives to be established for every type of health care practitioner who is subject to information blocking regulations. As the agencies work to develop additional disincentives for other types of practitioners, **we urge 1) implementation of a single corrective action plan (CAP) process for all health care practitioners, including remediation procedures through which information blocking issues can be resolved without a disincentive being issued; and 2) not removing physicians from value-based care arrangements as a penalty for information blocking**. The practice of removing clinicians from these arrangements directly contradicts the current administration's desire to hold clinicians accountable for their patients' health outcomes. The AAFP looks forward to continued collaboration with the agencies to support the expansion of value-based care nationwide, and we welcome the opportunity to further engage on identifying appropriate disincentives for physicians found guilty of information blocking.

While the AAFP agrees that appropriate disincentives must be in place to in order to facilitate information sharing and prevent information blocking by organizations or individuals, we continue to have serious concerns regarding some of the disincentives established in the June 2024 final rule. Some finalized provisions will negatively impact small and independent physician practices, while others will not be able to achieve the agencies' stated intent of

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deterring information blocking. The AAFP is concerned that the disincentives framework established in the June 2024 final rule disproportionately penalize independent, rural, and other under-resourced practices, particularly because of the all-or-nothing approach taken to clinician disincentives, regardless of whether information blocking was intentional or whether the actor has taken steps to address outstanding issues.

The AAFP urges the agencies to monitor whether the disincentives finalized in the June 2024 final rule are succeeding in sufficiently deterring information blocking by hospitals. Other penalties for hospital noncompliance of federal regulations have had to be strengthened to more effectively outweigh the competitive advantage of noncompliant behavior. Hospitals and health systems are significant sources of patient health data, particularly given recent consolidation in the health care market. Thus, it is important that disincentives drive compliance by these actors. The AAFP strongly urges the agencies to consider how the disincentives currently in place are likely to financially impact various types of health care practitioners.

PR–14. How can CMS encourage providers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would it advance or negatively impact data exchange?

The AAFP encourages the addition of an anticipated enforcement priority regarding intentional or "actual knowledge" instances of clinician information blocking. While we appreciate that the legal standard of intent differs between practitioners and health IT vendors, we also know that many instances of information blocking are unintentional. If intentional or "actual knowledge" was included as an enforcement priority, tracking and analyzing instances of intentional information blocking would be much simpler. This would also allow agency staff to more easily identify patterns in cases of unintentional information blocking and target educational outreach where it's shown to be most needed. Additionally, the AAFP urges CMS and ASTP/ONC to specify what plans and processes have been developed or implemented to ensure physicians will not be subject to erroneous duplicative penalties for single instances of information blocking. **Providing clarity in this area would support our shared values of accountability and transparency, as well as offering assurance to physicians and increasing their confidence in the reporting mechanism**.

Section: Value-Based Care Organizations; Subsection: Digital Health Adoption

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VB–1. What incentives could encourage APMs such as accountable care organizations (ACOs) or participants in Medicare Shared Savings Program (MSSP) to leverage digital health management and care navigation products more often and more effectively with their patients? What are the current obstacles preventing broader digital product adoption for patients in ACOs?

Delivering coordinated, high-quality patient care in value-based payment (VBP) models requires physicians to receive timely notification of the patients for whom they are responsible and have easy access to complete longitudinal patient information, including care provided in other settings. One of the obstacles we hear about most often from our members is their care team's lack of timely information on patients for whom they are accountable. Even when patients are offered the advantage of voluntary alignment, physicians do not always receive timely, actionable information for the patients attributed to them by different insurers. For more information on best practices regarding attributing patients to physicians within VBP models, please see the AAFP's Value-Based Primary Care Establishing Accountability Call-to-Action Brief.

The AAFP further believes that the complexity of value-based care delivery for primary care practices contracting with multiple payers – sometimes 10 or more – requires centralized, neutral, data aggregation support. Health information exchange (HIE) organizations are well-positioned to serve this purpose, but full participation in bidirectional exchange of information through these entities is under-leveraged in most states and communities. CMS and ASTP/ONC have a unique opportunity to increase the uptake in digital exchange for physicians and patients by more actively leveraging this existing infrastructure.

VB–2. How can key themes and technologies such as artificial intelligence, population health analytics, risk stratification, care coordination, usability, quality measurement, and patient engagement be better integrated into APM requirements?

Broadly speaking, the AAFP is not in favor of more requirements for APMs. The AAFP believes programs need to have flexibilities available to them for program design and participation, since a practice's needs vary based on a multitude of factors, including geographic location, patient population, and current payer market. Other than AI, the themes and technologies listed here are key components to successful participation in VBC arrangements. The AAFP supports

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continued flexibilities in how practices are permitted to execute on those components and be successful.

VB–3. What are essential health IT capabilities for value-based care arrangements? Examples (not comprehensive) may include: care planning, patient event notification, data extraction/ normalization, quality performance measurement, access to claims data, attribution and patient ID matching, remote device interoperability, or other patient empowerment tools. What other health IT capabilities have proven valuable to succeeding in value-based care arrangements?

The AAFP believes that all the examples listed above are accurate examples of essential health IT capabilities for VBC arrangements, as well as care management tools, patient/population identification and risk stratification models, population health analytics, health-related social needs assessments, and discharge planning and transitions of care models.

VB–4. What are the essential data types needed for successful participation in value-based care arrangements?

The AAFP strongly believes that information flows must be standardized, centralized, and bidirectional to reduce the current burdens associated with data collection and reporting requirements in VBP models. Centralized, bidirectional data flow is best facilitated using a payer- and physician-agnostic data intermediary that provides much-needed data governance and security functions for various sources of health data. Data intermediaries include HIEs and health data utilities (HDUs). These entities are essential to the creation of a person-centered data and information resource to support coordinated, comprehensive primary care.

The AAFP believes the following types of data are essential to enabling VBC success:

- Admission, discharge, and transfer notifications;
- Referral feedback and closure;
- Lab and imaging results;
- Medication fill notifications;
- Accurate and timely patient lists;
- Comprehensive patient demographic information and health status (risk level or score);
- Timely and frequent contractual performance feedback; and

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- Cost and quality information on network referral options.

Section: Value-Based Care Organizations; Subsection: Compliance and Certification

VB–5. In your experience, how do current certification criteria and standards incorporated into the ONC Health IT Certification Program support value-based care delivery?

We greatly appreciate this section's delving into the needed capabilities and functionalities of health IT to support VBC and VBP. Unfortunately, the current certification and standards are more focused on external data exchange and the automation of the business of health care, as opposed to the actual delivery of care. There are some certification criteria that support VBC delivery, such as in the United States Core Data for Interoperability (USCDI) Core, but there are many functionalities that are missing. Due to the complexity of these questions and the breadth needed to respond, the AAFP does not believe an RFI approach can succeed in getting the quality of discussion and recommendations these questions are owed.

Instead, we recommend HHS convene a summit (or potential series of summits) to bring together leading physician practices, health systems, and other providers alongside key industry stakeholders to explore, discuss, and build consensus around what is truly needed to support VBC and payment in our health care system. The AAFP recently hosted a broad multi-stakeholder summit focused on AI in primary care that was useful in crafting a shared vision and developing a collective strategy for achieving that vision. We look forward to sharing the findings and recommendations from the summit upon publication this summer. The AAFP stands ready to assist the Department in similar efforts related to the initiatives described in this RFI.

Conclusion

Thank you for the opportunity to provide comments on this RFI; the AAFP appreciates CMS and ASTP/ONC's efforts to better understand the current health technology ecosystem and to seek public recommendations on how technology can improve interoperability, support physician practices' transition to value-based care, and lead to better patient experiences and outcomes. We look forward to continuing to partner with CMS, ASTP/ONC, and other stakeholders to advance health IT tools for the betterment of patients, physicians, and the entire health care

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system. Should you have any questions, please contact Mandi Neff, Regulatory and Policy Strategist, at 202-655-4928 or mneff2@aafp.org.

Sincerely,

Steven Furr, MD, FAAFP
American Academy of Family Physicians, Board Chair

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[i] Alkureishi MA, Choo ZY, Rahman A, Ho K, Benning-Shorb J, Lenti G, Velázquez Sánchez I, Zhu M, Shah SD, Lee WW. Digitally Disconnected: Qualitative Study of Patient Perspectives on the Digital Divide and Potential Solutions. JMIR Hum Factors. 2021 Dec 15;8(4):e33364. doi: 10.2196/33364. PMID: 34705664; PMCID: PMC8675564.
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