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June 13, 2025

Robert F. Kennedy, Jr.
Secretary
US Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

RE: RIN 0938-AV68 Centers for Medicare & Medicaid Services Request for Information; Health Technology Ecosystem

Dear Secretary Kennedy:

On behalf of the American Health Information Management Association (AHIMA), we write in response to the Centers for Medicare & Medicaid Services and Assistant Secretary for Technology Policy/ Office of the National Coordinator for Health Information Technology (ONC) (ASTP/ONC) Request for Information (RFI); Health Technology Ecosystem published in the May 16, 2025 *Federal Register* (CMS-0042-NC).

AHIMA is a global nonprofit association of health information (HI) professionals, with over 67,000 members and more than 100,000 credentials worldwide. The AHIMA mission of empowering people to impact health® drives our members and credentialed HI professionals to ensure that health information is accurate, complete, available and trusted – enabling quality care for patients everywhere. Leaders within AHIMA work at the intersection of healthcare, technology, and business, occupying data integrity and information privacy job functions worldwide.

The following are our comments and recommendations on select questions within the RFI.

B. Patients and Caregivers

1. Patient Needs

PC-2. Do you have easy access to your own and all your loved ones' health information in one location (for example, in a single patient portal or another software system)?

The current health information technology (IT) ecosystem allows patients to access their health information in a variety of ways through different applications. Providing electronic access to this data is required for all certified health IT products as part of the 21st Century Cures Act interoperability final rule (Cures Act final rule) and required to be produced by covered entities and business associates when requested by a patient under the Health Insurance Portability and Accountability Act (HIPAA).[1] Today, many provider organizations make this information available through a patient portal. While patients may download some of the data contained within their health record – as required by the Cures Act Final rule – to the app of their choice, there is no singular solution that

[1]Available at: https://www.healthit.gov/topic/oncs-cures-act-final-rule.

enables a patient or their caregiver to access a patient's health data from multiple providers at the same time if a patient sees multiple providers at different health care organizations.

Patient portals, like Epic's MyChart solution, offer the ability for a patient to authenticate and access their health information. Multiple providers can be accessed by a patient through MyChart as long as they all utilize the Epic electronic health record (EHR) platform. That said, a patient must authenticate each provider separately to access the information and is not able to view information from multiple providers simultaneously. This is similar across other patient portal apps such as Oracle Health's Patient Portal, Meditech's MHealth app, and other apps that correspond to a respective EHR.

Furthermore, if a patient or caregiver is unable to access a smartphone, internet connected tablet, or internet connected computer they will not be able to access the information. As a result, they are left with having to accept access to their health information in the form of a CD-ROM or in paper format. Similarly, not all patient portal apps are made the same and for some applications, patient health information may require access via a computer as opposed to an app. While it may be easy to access this information as the patient, caregivers may struggle to access health information via an app or portal due to the proxy access requirements that are imposed at the state level.[2] **AHIMA recommends CMS and ASTP/ONC collaborate to determine positive incentives that encourage the creation of electronic patient-facing solutions to ease the burden of accessing their health information**.

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

The release of patient health data is governed by HIPAA and the 21st Century Cures Act. Under HIPAA, covered entities have 30 calendar days from receiving an individual's request for access to their protected health information (PHI) contained in a designated record set to provide such access. If a provider is unable to provide access within 30 calendar days, they have an additional 30 days if they have notified the requestor of the delay within the initial 30 days.[3]

Within the Cures Act final rule, information blocking actors are required to provide access to valid requests for health information from another actor without delay or interference.[4] What constitutes a "delay or interference" that rises to the level of information blocking is not defined. However, an organization must follow organizational policies and processes when fulfilling requests to demonstrate their actions do not constitute information blocking. There are a number of exceptions available to actors under the information blocking provisions that can provide additional time to respond to a request or permit an organization to not fulfill the request.[5] **AHIMA welcomes the opportunity to collaborate with CMS and ASTP/ONC on opportunities to improve patients' and caregivers' access to their health information.** This includes developing better guidance to assist actors with ensuring they are not engaging in information blocking. Since the Cures Act final rule was finalized, AHIMA and its members have been active participants in The Sequoia Project's Interoperability Matters Information Sharing Workgroup which has sought to develop resources for the field to support information blocking compliance. HI professionals remain the foremost experts available to provide insights on how to improve the release of information and patient data access processes and we welcome the opportunity to work with CMS and ASTP/ONC to improve existing workflows to provide such access.

[2]Available at: https://www.mychart.org/help/proxy.
[3]Available at: https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.
[4]Available at: https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7031.
[5]Available at: https://www.healthit.gov/faqs?f%5B0%5D=subtopic%3A7031.

PC-7. If CMS were to collect real-world data on digital health products' impact on health outcomes and related costs once they are released into the market, what would be the best means of doing so?

AHIMA recommends CMS undertake a formal notice of proposed rulemaking process related to the collection of real-world data on the impacts of digital health products on health outcomes and related costs. Digital health products are regulated by different agencies and impact a variety of healthcare treatments and services. It is important to understand the scope of the digital health ecosystem specifically related to outcomes and costs before implementing policies related to data collection activities. A robust public proposal and comment process will allow the health technology sector to evaluate the current landscape and provide recommendations to CMS on how best to proceed without duplicating existing efforts as to be unduly burdensome on digital health vendors and/or end-users of such products and services.

2. Data Access and Integration

PC-8. In your experience, what health data is readily available and valuable to patients or their caregivers or both?

HIPAA covered entities are required to give individuals access to their PHI, upon valid request.[6] Information a covered entity and/or their business associate is required to produce PHI contained in the designated record set. The designated record set is defined as "a group of records maintained by or for a covered entity that is: (i) the medical records and billing records about individuals maintained by or for a covered healthcare provider; (ii) the enrollment, payment, claims adjudication, and case or medical management record systems maintained by or for a health plan; or (iii) used, in whole or in part, by or for the covered entity to make decisions about individuals."[7] While healthcare organizations today are responsible for defining what is contained in their organization's designated record set, covered entities are required to provide access to an individual or potentially face a complaint and/or penalty from the HHS Office for Civil Rights (OCR).

Additionally, under the Cures Act final rule, actors must make available, without special effort, the electronic health information (EHI) when requested. EHI is defined as "the electronic protected health information (ePHI) to the extent that it would be included in a designated record set (other than psychotherapy notes or information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding) regardless of whether the group of records is used or maintained by or for a HIPAA-covered entity."[8] If an actor does not make EHI available for access, exchange, or use in response to a valid request then an actor could be found to be information blocking and could be subject to penalty. In 2021, AHIMA worked with the Electronic Health Record Association (EHRA) and the American Medical Informatics Association (AMIA) to develop industry guidance to assist health IT vendors and providers in standardizing data classes relevant to the designated record set and EHI to support operationalization of HIPAA and the Cures Act final rule and improve individuals' electronic access to their health information. **AHIMA welcomes the opportunity to collaborate with CMS and ASTP/ONC on policy solutions to further agency goals of improving patients' and caregivers' access to health information**.

PC-10. How is the Trusted Exchange Framework and Common Agreement™ (TEFCA™) currently helping to advance patient access to health information in the real world?

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[6]Available at: https://www.hhs.gov/hipaa/for-professionals/faq/2042/what-personal-health-information-do-individuals/index.html.

[7] 45 CFR 164.501

[8]Available at: https://www.healthit.gov/sites/default/files/page2/2021-12/Understanding_EHI.pdf.

AHIMA continues to be a supporter of the Trusted Exchange Framework and Common Agreement (TEFCA). Actively exchanging information since December 2023, the TEFCA processes the exchange of patient health data daily with the exchange facilitated by nine approved Qualified Health Information Networks (QHINs).[9] Additional QHINs are in the process of achieving approval to begin active data exchange on the TEFCA with the Oracle Health Information Network recently achieving candidate status to become a QHIN.[10] The TEFCA opens additional pathways for those engaged in health information exchange to connect with each other in a predictable manner and meet requirements under the Promoting Interoperability Program. TEFCA continues to make progress on its FHIR roadmap in order to align its exchange standards with those mandated for the Health IT Certification Program and AHIMA remains a supporter of this approach.[11]

In both the health technology and interoperability rulemaking processes, HTI-1[12] and HTI-2[13], AHIMA provided comments on how to support TEFCA via regulatory policies. AHIMA recommends ASTP/ONC preserve a predictable cadence of updates to the TEFCA and its corresponding policies. Such predictability will enable the provider sector to prepare for and adopt TEFCA broadly and foster a stable network with a predictable path forward for implementation and use. As ASTP/ONC continues implementation activities with the TEFCA, AHIMA and its membership remain engaged supporters with an active interest in participating in continued development activities.

As efforts to improve nationwide health information exchange nationwide continue, AHIMA recommends HHS pursue expanding use cases to include additional non-clinical data exchange processes. Existing activities, such as prior authorization, could be made less burdensome if established data exchange networks expanded to include data exchange for these processes. Utilizing the strong, nationally supported networks, such as TEFCA, will be crucial for the nation to continue advancing patient data exchange.

AHIMA and its membership, who are actively engaged in the health information exchange process, remain ready to assist CMS and ASTP/ONC in its continued work on advancing nationwide health information exchange.

PC-12. What are the most valuable operational health data use cases for patients and caregivers that, if addressed, would create more efficient care navigation or eliminate barriers to competition among providers or both?

The ability of providers and healthcare organizations handling health information to accurately match patients to their medical records where and when they need them continues to be a struggle throughout healthcare. Demographic health data elements can be used as a powerful tool to improve accurate identification of patients to their records. This includes the data elements, contained with the United States Core Data for Interoperability (USCDI).

The USCDI plays a key role in implementing standardized data elements in certified health IT products, leading to improved interoperability and exchange. AHIMA, along with the Patient ID Now Coalition,[14] believes studying the

[9]Available at: https://rce.sequoiaproject.org/designated-qhins/.
[10]Available at: https://www.oracle.com/news/announcement/oracle-health-information-network-achieves-candidate-status-for-tefca-qhin-2025-05-08/.
[11]Available at: https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/.
[12]Available at: https://www.ahima.org/media/ecslk3zh/ahima-final-comments-astp-hti-2-proposed-rule.pdf.
[13]Available at: https://www.ahima.org/media/ecslk3zh/ahima-final-comments-astp-hti-2-proposed-rule.pdf.
[14]Available at: https://patientidnow.org/.

USCDI to determine which elements with corresponding standards can be used together as a dataset to accurately identify and match patients to their records is a common sense solution to solving the nation's patient matching crisis. HR 2002, the Patient Matching and Transparency in Certified Health IT (MATCH IT) Act of 2025[15] was introduced to direct ASTP/ONC and HHS to do this exact work.

The MATCH IT Act has four tenets aimed at improving patient identification and matching by improving standardization of demographic data elements within health records. This legislation: (i) defines a patient match rate, (ii) establishes an industry standard data set to improve patient matching, (iii) updates health IT certification requirements to include the established data set, and (iv) leverages CMS' Promoting Interoperability Program to encourage the utilization of these data elements and patient matching frameworks. ASTP/ONC is also directed to coordinate with other federal partners to create an anonymous voluntary reporting program for providers to submit matching accuracy data to HHS for the agency to understand the impact of patient matching long-term.

Patient matching errors can be addressed through approaches like those outlined in the MATCH IT Act. AHIMA encourages the Administration to continue to address patient identification and matching through improving definitions and standardization, including standardization within USCDI. Patients, caregivers, and providers will have an improved experience with the healthcare system if they can trust that the record in front of them is correct, leading to increased trust in both the health information and the care provided.

C. Providers

1. Digital Health Apps

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?

The administrative burden placed on providers with the advent of EHRs has been well documented.[16] Initial investment contained in the HITECH Act has assisted healthcare organizations in making tremendous strides in moving from paper-based records systems to one almost entirely digitized.[17] However, digitization has not been without its challenges, including the strict regulatory EHR certification requirements, implemented by ASTP/ONC and enforced by CMS, for new technologies and a limited marketplace of developers able to meet those requirements.

One example of a process falling victim to these challenges is the prior authorization process.[18] The process of filing a prior authorization request and achieving a decision is a delicate dance between the ordering physician, HI professional, and payer often involving multiple portals, phone calls, faxes, and multiple parties reading the contents of a patient's record. With a complex mix of regulatory and payment incentives for providers, technology developers, and payers, the responsibility for solving the time burden associated with the prior authorization process is passed from party-to-party with no clear solution. The result of which can at times lead to delayed or

[15]Available at: https://www.congress.gov/bill/119th-congress/house-bill/2002/text.
[16]Available: https://kffhealthnews.org/news/death-by-a-thousand-clicks/.
[17]Available at: https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.
[18]Available at: https://www.ey.com/en_us/insights/health/how-electronic-prior-authorization-can-help-health-care.

denied treatment of patients. While there have been efforts to alleviate the burden associated with this process, many of them are ill-equipped, lack technical readiness, or worsen the process at the root of the problem.[19]

Prior authorization is just one example of several electronic processes in healthcare that have digital solutions that do not adequately address process challenges. The standards utilized to enable prior authorization have largely been created in a vacuum with little input by those who will ultimately use the technology. This has led to standards that were not tested in real world environments before being pushed to production. This leads to increased burden on the users of the standards and technology that do not achieve the policy goals they were designed to meet. The users of these new technologies and workflows – such as those created for prior authorization – should be included in all phases of development to raise the chances of such standards being adopted more broadly by end-users.

AHIMA recommends CMS and ASTP/ONC work to identify and mitigate the underlying workflow, regulatory, and incentive problems in addition to considering technical solutions to these challenges. AHIMA welcomes the opportunity to collaborate with CMS and ASTP/ONC on potential solutions to lessen the burden of existing prior authorization processes.

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)?

The more trusted, accurate data a provider has available about a patient helps paint a more complete picture of a patient's health. This is true for all providers regardless of setting. The advancement of EHRs and health data exchange has improved the amount of data a provider has available for decision-making. Despite progress, challenges in technical, regulatory, and practical areas persist in accessing all of a patient's health information from all of their providers.

The technical limitations for making all patient data available for exchange originates within the segmented systems a provider organization utilizes to provide each facet of care. While an EHR may function as a "source of truth" for a patient's health history, there exist innumerable other systems throughout a provider facility that also hold information about a patient's care.[20] For example, patient's labs or radiology imaging data may be held in systems separate to the EHR. This stems from the need for some data to remain on the system it was generated on in order to be read, such as an MRI scan, as well as the fact that EHRs may not have structured standardized ways to store that data.

Challenges of data size and weight also impact the ability for data to be stored in one place. This includes complexities relating to internet bandwidth and the type of data being transmitted. Individual structured data elements create a predictable environment for data to be exchanged through traditional networks with standard bandwidths. Exchanging a series of MRI images or x-rays, for instance, requires faster internet speed compared to exchanging a patient's vital records or visit summaries. Many providers, both rural and urban, lack access or funding to utilize broadband internet pipelines suitable for the rapid and constant exchange of large pieces of medical data, such as images. Without continued federal support, such as the discontinued Federal

[19]Available at: https://www.ahima.org/media/lzgbwjad/ahima-electronic-prior-authorization-rfi.pdf.
[20]Available at: https://sequoiaproject.org/wp-content/uploads/2022/08/EHI-TG-Workstream_3-Infographic-FINAL.pdf.

Communications Commission (FCC) Affordable Connectivity Program,[21] the bandwidth to facilitate this exchange inhibits the ability to exchange such data.

Finally, while increasing the amount of data being exchanged is a laudable goal, the reality is there are fundamental considerations related to technology that must addressed first. As the Change Healthcare cyberattack in 2024 demonstrated, much of the healthcare system is reliant on a handful of technologies and, in some instances, just one.[22] Tremendous strides have been made in achieving widespread interoperability, however, healthcare is still not entirely interoperable and dominated by a few technical solutions. For digital healthcare to continue advancing we must diversify technical offerings to ensure healthcare mitigates the risk of single digital points of failure. Solutions are also needed to close the last mile of providers unable to exchange data interoperably, while increasing the number of standardized data elements an EHR can capture.

AHIMA and its membership stand ready to assist CMS and ASTP/ONC in the search for technical, regulatory, and industry solutions to these complex problems.

2. Data Exchange

PR-5. Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:

Eligible hospitals and providers utilizing certified electronic health record technology (CEHRT) were required to adopt the Provider Directory API by July 1, 2021 to maintain compliance under the Promoting Interoperability Program.[23] Similarly, the clinician decision support (CDS) hooks technical requirements were required to be implemented by January 1, 2025 and have achieved compliance, if required, under the Promoting Interoperability Program.[24] Other technology APIs, such as the Patient Access API, standardized API for patient and population services, Prior Authorization APIs, Bulk FHIR, and SMART on FHIR have yet to reach the federally mandated implementation deadlines. Compliance will be achieved by eligible hospitals and providers by the corresponding deadlines in 2026 and 2027 if organizations maintain compliance with the Promoting Interoperability Program.[25]

In most cases, if not all, providers are reliant on the delivery of updated certified products from their health IT vendors to achieve implementation of the technologies described above and to maintain compliance with federal regulations. At the same time, provider organizations, especially smaller practices, are not always able to dictate when and in what means they receive new technologies within their EHRs. As a result, ensuring health IT systems have updated their certified products consistent with an appropriate timeline is a necessary component to ensuring that provider organizations are able to take advantage of FHIR APIs and related capabilities that enable them to comply with CMS requirements such as the Promoting Interoperability Program. We encourage CMS and ASTP/ONC to work with the health IT vendor community to ensure that any new technical standards and/or capabilities are operational, scalable, and usable prior to provider implementation.

[21] Available at: https://www.fcc.gov/acp.
[22] Available at: https://ahima.org/media/2ldik2jy/joint-letter-on-strengthening-healthcare-infrastructure-in-response-to-change-healthcare.pdf.
[23] Available at: https://www.cmsinteroperability.org/provider-directory.
[24] Available at: https://www.healthit.gov/sites/default/files/2023-10/CDS%20Hooks%20and%20SMART%20apps-part1_508.pdf.
[25] Available at: https://www.healthit.gov/sites/default/files/2024-03/Overview-and-Key-Dates-2024_508.pdf.

Finally, the APIs mandated for implementation within the CMS Interoperability Patient Access final rule[26] implementation guides lag the necessary timelines to achieve successful implementation.[27] To better support the development of these APIs and corresponding implementation guides, we encourage CMS and ASTP/ONC to work with FHIR accelerator projects, such as the HL7 Da Vinci Project, to ensure resources are available for the development of these technologies to continue. Without the completed implementation guides the APIs themselves will make it more difficult for implementation by the deadlines outlined within regulation.

PR-6. Is TEFCA currently helping to advance provider access to health information?

Providers eligible to participate in the TEFCA are actively exchanging data on the network. CMS has incentivized the provider community to participate in TEFCA through the Promoting Interoperability Program with an optional measure relating to health information exchange.[28]

The TEFCA network of QHINs is broad, and a majority of providers are estimated to be connected to a national network with access to nationwide healthcare exchange.[29] This network will only become more inclusive as additional QHINs, such as Oracle Health Information Network, are approved. With the TEFCA continuing down the pathway of implementation, additional pathways for patients, as well as non-provider entities, will begin to become available. This will increase the ability for all parties to access and exchange patient data in a trusted, secure manner.

AHIMA recommends HHS continue to support the implementation of the TEFCA. With few options for nationwide health data exchange, the TEFCA is a crucial component to improving nationwide interoperability. While some vendors offer nationwide exchange capabilities, and other networks do exist, the TEFCA brings all crucial parties to the table by establishing common guardrails and requirements to ensure the data exchange landscape does not fragment between vendors or required extensive workarounds to move data.

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?

Healthcare organizations face several challenges and barriers to collecting and sharing high-quality data including variability and lack of standardization in data collection and management processes and hospital rating systems, causing inconsistencies in how data is documented and shared both within and across organizations and reduced data usability. Organizations also face challenges of regulatory burden from compounding requirements regarding new technology and standards, which is exacerbated by the lack of adequate workforce support for HI professionals and other health IT end-users who are directly involved with implementing new and changing requirements. Healthcare organizations also face privacy and security challenges, especially considering the rise in non-HIPAA-protected health information held in patient-facing apps and technologies.

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[26] Available at: https://www.cms.gov/priorities/burden-reduction/overview/interoperability/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f

[27] Available at: https://confluence.hl7.org/spaces/DVP/pages/21857598/Da+Vinci+Implementation+Guide+Dashboard.

[28] Available at: https://www.healthit.gov/buzz-blog/blog-series-cms-ipps-rule/interoperability-in-action-cms-rule-builds-on-onc-initiatives-to-simplify-health-information-exchange.

[29] Available at: https://hitconsultant.net/2024/01/29/qhins-improve-healthcare-interoperability/.

To foster strong data quality in healthcare, CMS should consider conducting a survey to assess workflows, data governance processes, and barriers to data quality and sharing to understand shared industry challenges and successes. With that information, CMS and ASTP/ONC should pursue policies that promote the adoption of technologies that support high-quality data collection and a base level of standardization across EHRs, which may include standardized fields as part of the Health IT Certification program. CMS and ASTP/ONC should also support incentives for workforce development to support the success of such policies and maintain data quality and integrity as technology evolves.

HI professionals require resources and support in operationalizing best practices in data quality and integrity. While some organizations have training on data governance and quality, many organizations are limited in resources to do so. AHIMA stands ready to partner with CMS and ASTP/ONC to provide industry education and resources to healthcare providers on best practices related to data quality, literacy, and governance to ensure all healthcare organizations, regardless of size, financial resources, or geographic location, can confidently establish baseline data policies that are industry aligned. As HI professionals face a growing set of federal mandates, AHIMA encourages CMS to consider areas where documentation requirements can be standardized and streamlined across quality reporting programs to reduce burden and enable healthcare organizations to focus on collecting quality patient health information that is usable and shareable. AHIMA encourages CMS to include HI professionals in the different phases of policy development, including real-world testing of new initiatives before mandating in policy to ensure programs are functioning as intended with minimal burden, which will save the healthcare industry valuable resources over time.

Additionally, CMS should explore utilizing the Promoting Interoperability Program as a policy lever to incentivize the implementation of the Sequoia Project's Data Usability Implementation Guide v2.[30] CMS can improve the broad use of high-quality standards-based data by including the implementation of this guide as an optional incentive measure in Promoting Interoperability. With positive incentives to use implementation guides, such as the Data Usability Implementation Guide, CMS can assist providers in driving the use of trusted standardized data as part of health data exchange.

It is crucial for CMS to maintain a close working relationship with ASTP/ONC to ensure the provider is supported in the continued advancement of health data exchange and interoperability. While providers have some opportunity for input, such as via the Health IT Advisory Committee (HITAC), regulations finalized by ASTP/ONC govern technology developers and vendors, not providers. This leaves providers with limited ability to meaningfully advocate for changes to the certified technology they are required to use. Additionally, the non-clinical data space remains largely unregulated. It will be crucial for end-users, including HI professionals, to be at the table as CMS looks to engage in non-clinical technology activities in healthcare. AHIMA welcomes the opportunity to collaborate with CMS and ASTP/ONC on regulatory, technical, and industry solutions to address these challenging issues.

4. 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?

[30] https://sequoiaproject.org/interoperability-matters/data-usability-workgroup-implementation-guide-version-2/

AHIMA appreciates ASTP/ONC's continued attention to information blocking. In prior years, revisions to the exceptions have been made with little clarity on how they would impact front-line end-users and created additional ambiguity on how they would interact with or contradict existing laws and regulations.

For example, a recently added condition to the Privacy Exception allows actors to choose not to provide access, exchange, or use of an individual's EHI if doing so fulfills the wishes of the individual. We appreciate ASTP/ONC broadening the exception to assist actors in honoring requested restrictions. However, concerns remain about the unintended legal consequences for actors who restrict the sharing of EHI under the information blocking rule that may be contrary to existing law, and the downstream impact to patient safety if information sharing across the care team is restricted.

Furthermore, adding more exceptions to the information blocking program increases the complexity of the requirements actors are to comply with and risks undermining the intent of the program – to reduce unnecessary and unlawful inhibitions of access, exchange, and use of EHI. **AHIMA encourages ASTP/ONC to ensure that any revisions to the information blocking exceptions or conditions be simplified and streamlined to provide better clarity to end-users for compliance purposes.** This includes the privacy-related exceptions, such as this above example, and others finalized in the HTI-3 Final Rule.[31] AHIMA looks forward to working with ASTP/ONC to provide additional resources and education for healthcare organizations on potential changes in policies and workflows that may be needed to accompany proposed modifications to the exceptions.

D. Payers

PA-1. What policy or technical limitations do you see in TEFCA? What changes would you suggest to address those limitations? To what degree do you expect these limitations to hinder participation in TEFCA?

There are currently six approved exchange purposes under the TEFCA framework.[32] Those exchange purposes include treatment, payment, healthcare operations, public health, government benefits determination, and individual access services (IAS). Some health insurance payment processes are included in the exchange purposes – such as those included under healthcare operations – while others have yet to be codified via updates to the trusted exchange framework (TEF) and common agreement (CA). These two documents govern the operations of the TEFCA. Updates to include additional health insurance payer processes would allow the TEFCA QHINs to begin the adoption and implementation of additional exchange purposes.

AHIMA recommends ASTP/ONC and The Sequoia Project, operating as the Recognized Coordinating Entity (RCE), explore additional exchange purposes to support CMS' data exchange priorities. This includes exploring the ability for the TEFCA to support the data exchange processes outlined in the CMS Interoperability and Prior Authorization Final Rule.[33] Some EHR vendors have included connections to the TEFCA within their platforms to support health insurance payment processes. Continuing to utilize the TEFCA as a tool to meet the needs of these processes would create a standardized, widely adopted network solution to increase the amount and speed of payment-focused data exchange. The TEFCA presents a tremendous opportunity for CMS to advance many of its data exchange priorities quickly at scale with trusted, tested technology.

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[31]Available at: https://www.ahima.org/media/ecslk3zh/ahima-final-comments-astp-hti-2-proposed-rule.pdf.
[32]Available at: https://rce.sequoiaproject.org/exchange-purposes-explained/.
[33]Available at: https://www.cms.gov/priorities/burden-reduction/overview/interoperability/policies-and-regulations/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f/cms-interoperability-and-prior-authorization-final-rule-cms-0057-f.

PA-4. What would be the value to payers of a nationwide provider directory that included FHIR end points and used digital identity credentials?

AHIMA supports the development of a nationwide provider directory with endpoints. Creation of such a network would simplify the regulatory space for providers and healthcare organization, allowing easier navigation of the health data exchange landscape. In 2022, AHIMA provided comments to a CMS RFI on a national directory of healthcare providers and services.[34] Many of AHIMA's comments remain relevant today, including the need for the development of such a network to explore all technical options, including FHIR, to ensure the best technology solution is selected.

AHIMA also recommends CMS explore the ability for the TEFCA to host such a solution. While TEFCA is adopting the use of FHIR for its nationwide network, other technical standards that are prevalent in the healthcare ecosystems are also used to support the TEFCA, such as Integrating the Healthcare Enterprise (IHE) profiles.[35] With the TEFCA becoming widely adopted, an embedded national provider directory would have the ability to scale rapidly.

Creation of a nationwide provider directory would enable both providers and payers to seamlessly identify exchange partners throughout the nation. Enabling easy access to API endpoints helps improve trust in the data exchange itself while eliminating the time-consuming process of contacting prospective exchange partners. Additionally, such a directory could enable a better public health surveillance landscape, making it easier for organizations to do public health reporting.

AHIMA recommends CMS and ASTP/ONC work with The Sequoia Project, acting as the Recognized Coordinating Entity, to further the implementation of FHIR and its potential use cases, such as a national provider directory, within TEFCA. As the TEFCA continues to add additional use cases to its portfolio, such as those to support payment specific services, payers will continue to adopt TEFCA. The addition of services such as national provider directory services would hasten that adoption and allow payers to have one single network solution to address its data exchange and directory needs.

E. Technology Vendors, Data Providers, and Networks

3. Technical Standards and Certification

TD-4. How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?

Ensuring the nation's health system is not reliant on a single, or handful, of technologies is crucial to guard against single points of failure in the data exchange environment. The use of open, publicly available standards, including APIs, is one strategy to create a more diverse technical environment with multiple technical options for each need. CMS can incentivize the use of these types of standards-based open APIs by continuing to support the ASTP/ONC programs currently in place and by seeking new pathways to incentivize the use of these open-standard technologies. Those incentives should also include seeking the input of those actively using the technology post implementation. The benefit of using open standard APIs is that it provides those using the technology within provider settings an avenue to provide feedback throughout the development process to ensure the standards

[34]Available at: https://ahima.org/media/mmkkaag0/final-ahima-cms-national-provider-directory-api-comments.pdf.
[35]Available at: https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/.

meet the desired policy goals. By including end-users throughout the development process, including a robust testing process, CMS can ensure the standards are sufficiently mature prior to mandating such standards in regulation.

AHIMA recommends CMS continue to its strategy of encouraging the adoption of certain technologies with positive incentives and penalties as it has a proven track record of success with the rapid high rate of CEHRT adoption.[36] Prior adoption was driven by the Promoting Interoperability Program incentivizing the use of this technology as part of Medicare reimbursement, while also handing out negative Medicare payment adjustments for those who did not adopt the necessary technology.

Partnering with ASTP/ONC to ensure the CEHRT updates include open, standards-based APIs and incorporating those updates as requirements within active CMS programs is the best option for encouraging use of the APIs. Expanding CMS' authorities as it relates to requiring the implementation of certain technologies would also give CMS the ability to incentivize, or require, the use of open standards-based APIs.

TD-5. How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?

AHIMA supports the development of a nationwide provider directory of endpoints to improve access to health information for patients, providers, and payers.[37] If CMS were to support the development of a network of endpoints we recommend a notice of formal request for information on this topic to solicit feedback from the health IT community on how best to publish a directory and who should oversee its development and maintenance. The TEFCA is a widely used network of networks with broad adoption that could be used as the foundation for a provider endpoint directory. CMS should assess whether the cost of the proposed provider directory could be absorbed by the existing TEFCA framework and/or TEFCA fee framework.

At the same time, it is important for CMS to examine existing industry solutions to understand the gaps a provider directory could fill. This includes CAQH's provider director management solution, among others. To minimize the burden of those that utilize healthcare technologies, we must ensure any new technologies are filling an unmet need. **AHIMA welcomes the opportunity to collaborate with CMS and ASTP/ONC as it seeks to create a national provider directory.**

TD-6. What unique interoperability functions does TEFCA perform?

Beyond TEFCA, there are few options for nationwide health data exchange that include all data exchange parties. The lack of existing options to enable widespread data exchange can be burdensome on EHR vendors and others in having to facilitate separate data exchange processes for HIEs and HINs, healthcare organizations, Direct Messaging partners, and individual patients. The TEFCA framework brings together these critical parties and promotes interoperability between vendors, ensuring quicker, more seamless, and trusted data exchange. AHIMA recommends CMS and ASTP/ONC continue to support implementation of TEFCA to promote efficient interoperability between vendors and networks for improved data exchange.

[36]Available at: https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.
[37]Available at: https://ahima.org/media/mmkkaag0/final-ahima-cms-national-provider-directory-api-comments.pdf.

The six authorized exchange purposes under the TEFCA framework are a good start in building a robust network of data exchange for these essential purposes. It is well understood within the healthcare industry that prior authorization processes are burdensome for all parties involved including end-users, payers, and technology vendors. As TEFCA continues to develop and expand, AHIMA encourages ASTP/ONC and The Sequoia Project to explore the use of TEFCA to support prior authorization processes. Including prior authorization as an exchange purpose under TEFCA can streamline the process, which can significantly reduce the associated administrative burden and improve participation in TEFCA. Such a prior authorization exchange purpose could begin as voluntary, which would allow participants to become familiar with the TEFCA operational network. Then when appropriate, with industry readiness and consensus-driven standards, ASTP/ONC and The Sequoia Project could explore transitioning this exchange purpose to one with a required response. **AHIMA welcomes the opportunity to collaborate with CMS and ASTP/ONC as each agency seeks to solve these complex technology issues.**

TD-7. To what degree has USCDI improved interoperability and exchange and what are its limitations?

The USCDI has made strides in improving interoperability and exchange, and AHIMA supports ASTP/ONC's continued expansion and advancement of USCDI through the regular addition of data classes and elements. The cyclical nature of updates to USCDI is helpful for ensuring certified technology continues to meet the needs of end-users, including HI professionals. However, many of the elements within USCDI (e.g., first name, last name, and date of birth) do not have corresponding standards that dictate how these data should be entered, which creates challenges in data usability and care coordination. Adding data elements to USCDI with corresponding standards would be valuable in promoting streamlined data exchange.

Ideally, standards are created to meet the needs of health IT end-users, particularly HI professionals, who are directly involved with these data documentation and exchange processes. While HL7 makes available space for providers to participate in the standards development process, it can be difficult for end-users to take time away from their critical roles within their organizations to participate. AHIMA recommends ASTP/ONC engage with the end-user community to determine optimal ways to involve these individuals earlier in the standards development process. With early and robust participation, HI professionals and others are better prepared for the addition of USCDI data elements in CEHRT and ensures the standardized data exchanged is effective and usable. **AHIMA and its membership stand ready to assist CMS and ASTP/ONC as they seek to maximize the utility of the USCDI and its corresponding process.**

TD-9. Regarding certification of health IT: a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality? b. What would be the drawbacks? c. How could ASTP/ONC revise health IT certification criteria to require APIs to consistently support exchanging data from all aspects of the patient's chart (for example, faxed records, free text, discrete data)? d. What policy changes could CMS make so providers are motivated to respond to API- based data requests with best possible coverage and quality of data? e. How could EHRs capable of bulk data transfer be used to reduce the burden on providers for reporting quality performance data to CMS? What capabilities are needed to show benefit? What concerns are there with this approach?

Shifting the Health IT Certification Program from certifying EHRs to certifying the APIs may require congressional action. The Health Information Technology for Economic and Clinical Health Act HITECH Act, as enacted by Congress as part of the American Recovery and Reinvestment Act (ARRA), states:

> "*The National Coordinator shall support the development and routine updating of qualified electronic record technology (as defined in section 3000) consistent with subsections (b) and (c) and make available*

such qualified electronic health record technology unless the Secretary determines through an assessment that the needs and demands of providers are being substantially and adequately met through the marketplace."[38]

ARRA defines qualified electronic record technology as:

> *"An electronic record of health-related information on an individual that (A) includes patient demographic and clinical health information, such as medical history and problem lists; and (B) has the capacity (i) to provide clinical decision support; (ii) to support physician order entry; (iii) to capture and query information relevant to healthcare quality; and (iv) to exchange electronic health information with and integrate such information from other sources."*[39]

Moving to such a strategy focused on APIs instead of EHRs could open up the ability for ASTP/ONC to more stringently govern how data is transported instead of sent and received. This creates opportunities to further introduce a broader community of technology developers beyond the traditional EHR vendors that currently operate in healthcare as a benefit of their certified statuses.[40] This could in turn create additional market supply for technology developers and cause the cost for purchase and implementation of EHR technologies to decline.

At the same time, certifying APIs versus software functionality also creates challenges. Moving away from certifying EHRs could limit the ability of ASTP/ONC to regulate the way data is captured within the EHR separate from the standards used to transmit the data. An API may translate data into a transportable format, but it could cause an EHR system's front-end to capture basic health data differently. This mean providers would need to have specialized training for each organization they work at as the EHR implemented may capture patient information differently. Additionally, moving to a certification model focused on APIs limit the ability of the payer and end-user communities from providing input into the certification process as the focus would be on areas of health information exchange payers and providers have no active role in, but are majorly impacted by. While APIs may provide the connections for payer and healthcare organizations, how the information is transferred often falls outside of those organizations' expertise and purview. This could create uncertainty in the end-user and payer communities, potentially slowing down the speed of innovation or new products.

Outside of the broader ecosystem drawbacks of moving to an API certification model, the biggest challenge to moving to focus on API-enabled capabilities versus software functionality is that the FHIR APIs themselves are not currently ready for scalable implementation. Both the Bulk FHIR and the EHI Export APIs are not fully operational with significant lag times needed for the implementation guides to be finalized.[41] A significant cost burden would be placed on the healthcare sector to make the bulk data movement and EHI Export APIs operational and scalable. This includes adequate investment for end-users to adopt such APIs as organizations that have adopted these APIs are limited. Such challenges expand beyond the health data exchange space, with the bulk transfer and quality measure reporting API technology in need of rapid advancement to meet the needs of the community. **AHIMA welcomes the opportunity to discuss the operational opportunities and challenges of moving to a certified API model with CMS and ASTP/ONC.**

[38]42 USC § 300jj-17(a)
[39]42 USC § 300jj -13
[40]Available at: https://chpl.healthit.gov/#/search.
[41]Available at: https://confluence.hl7.org/spaces/DVP/pages/21857598/Da+Vinci+Implementation+Guide+Dashboard.

TD-10. For EHR and other developers subject to the ONC Health IT Certification Program, what further steps should ASTP/ONC consider to implement the 21st Century Cures Act's API condition of certification (42 U.S.C. 300jj-11(c)(5)(D)(iv)) that requires a developer's APIs to allow health information to be accessed, exchanged, and used without special effort, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws?

AHIMA recommends CMS and ASTP/ONC consult with HI professionals across healthcare prior to opening the entire EHR for access via API to determine the feasibility of implementing such a policy. Opening up full record access via API could create significant risks as it relates to the trustworthiness of data, the ability to track who has accessed a patient's data, and for correcting errors in the record that were inserted via API access. The process for correcting an error in a patient record is already onerous and becomes more difficult if an error proliferates across multiple organizations and records. Provider organizations are also required to maintain audit controls on who accesses a patient's data as part of HIPAA Security Rule compliance.[42] Opening access via API without proper considerations for audit controls would make compliance with these requirements difficult for providers, and hinder their ability to maintain compliance with the HIPAA Security Rule. HI professionals can assist with helping to mitigate these challenges and identifying additional considerations for CMS and ASTP/ONC to ensure they are properly mitigated if this policy proposal is pursued.

TD-11. As of January 1, 2024, many health IT developers with products certified through the ONC Health IT Certification Program are required to include the capability to perform an electronic health information export or "EHI export" for a single patient as well as for patient populations (45 CFR 170.315(b)(10)). Such health IT developers are also required to publicly describe the format of the EHI export. Notably, how EHI export was accomplished was left entirely to the health IT developer. Now that this capability has been in production for over a year, CMS and ASTP/ONC seek input on the following: a. Should this capability be revised to specify standardized API requirements for EHI export? b. Are there specific workflow aspects that could be improved? c. Should CMS consider policy changes to support this capability's use?

AHIMA recommends CMS and ASTP/ONC evaluate the success of the implementation of the EHI export functionality to determine the challenges and successes of the technology. The full EHI export functionality has only been in place for one year and many organizations have only been able to use such functionality for less than a year due to the time required to update an EHR system to implement new technology advancements. Patient utilization and knowledge of this functionality is also currently limited, with few patient-facing apps or programs able to accept this information and little available patient education on the functionality.

AHIMA members have shared their experiences regarding the lack of readiness for the EHI Export technology at the provider level. Multiple members have indicated to AHIMA that the EHI Export technology is not ready for implementation and fails to meet the basic goals of allowing full sets of patient data to be exported to a third-party app or into a file. None of the members AHIMA has spoken to have indicated they were given a clear implementation pathway or development roadmap to achieving the goals of full EHI Export.

If ASTP/ONC were to pursue changes to the requirements, we urge that end-users be included as part of the discussion early in the regulatory development process. While end-users have had opportunities to provide feedback to CMS and ASTP/ONC on the revised certification criteria, it has consistently been at the end of the full technology development process, leaving minimal opportunity for meaningful impact. If the EHI export

[42] Available at: https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html.

requirements were to be reexamined, it is crucial end-users are consulted early for CMS and ASTP/ONC to achieve the desired policy outcomes.

4. Data Exchange

TD-13. What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?

The existing market for patient-facing apps to hold and manage a patient's health data is limited. Patients often need to use multiple portals across multiple providers to access all their health information. An API with full access to a patient's EHI could foster a marketplace for patient-facing solutions allowing patients to collate all the information from all of their portals into one place and in a usable format. Full API access to health information could also create new pathways for health insurance payers and providers to exchange and utilize a patient's data in a manner that paints a more complete picture of the patient.

At the same time, complete access to a patient's data also raises considerations related to patient safety. The APIs themselves, as currently envisioned, allow access to a full patient's EHI but many of the APIs act as "read-only" APIs without the ability to correct information that is outdated or incorrect in another organization's EHR. This in turn creates a risk where an individual relying on the data in the app does not have the most up-to-date information regarding the diagnoses and treatment. For example, a situation could exist where a patient's allergy list or medication list is not properly updated, or worse, overwritten, causing a medication to be administered that causes a negative health outcome. Outdated or incorrect information could be transmitted from organization-to-organization in perpetuity without the ability of that information to be removed or updated.

Should ASTP/ONC and CMS seek to expand access to the entirety of a patient's EHI, AHIMA recommends both agencies undergo an extensive public feedback process with specific questions asked related to desired functionality. Those that utilize these technologies daily can provide robust feedback on specific proposals from ASTP/ONC and CMS allowing both agencies to undergo a path to successfully achieve the intended policy goals. Additionally, prior to undergoing that feedback process, CMS and ASTP/ONC should identify whether the EHI Export requirements, referenced in this RFI above, are substantively different than those discussed within this section of the RFI and whether adjustments need to be made to accomplish CMS and ASTP/ONC's desired policy goals.

TD-15. Regarding bulk FHIR APIs: a. How would increased use of bulk FHIR improve use cases and data flow? b. What are the potential disadvantages of their use?

Bulk FHIR APIs continue to be a promising advancement in FHIR technology that may limit the burden placed on provider organizations to export both large datasets and quality data. This requirement in CEHRT furthers the goal of ASTP/ONC of utilizing FHIR as a standardized solution for transporting health data and other health-related information. At this time, however, it is difficult to assess the potential improvements Bulk FHIR APIs may provide to healthcare due to their limited utilizations and recent implementation.

In addition to the recent implementation of the technology, cohorts of users determining full functionality of Bulk FHIR have only just begun their work.[43] With Bulk FHIR and its functionality in its infancy there have been growing

[43]Available at: https://www.ncqa.org/blog/introducing-the-first-cohort-of-the-bulk-fhir-quality-coalition/.

pains in the development of the APIs. To fully determine the potential of Bulk FHIR, users of the technology will need time to evaluate its usefulness, collaborate on solutions, and publish those findings for evaluation.

Finally, the utilization of Bulk FHIR is limited to only a subset of the healthcare ecosystem. One area where Bulk FHIR is most useful would be in quality reporting, or public health reporting. At this time however, only a small subset of providers possess the technology needed to utilize Bulk FHIR and few, if any, public health agencies or quality reporting organizations have the ability to receive Bulk FHIR data transfers. Until Bulk FHIR is proliferated throughout the healthcare system its capabilities will not be usable as intended. AHIMA recommends ASTP/ONC and CMS wait for further Bulk FHIR API development to mature before pursuing additional opportunities.

TD-17. Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing networks, including enough supply and demand, that results in usage and outcomes?

Healthcare providers incur significant costs in the adoption, use, and maintenance of CEHRT. In addition to the costs associated with purchasing new or upgrading existing technology, costs include changes to workflows, hardware updates, data migration, and education for providers and staff. Both rural and urban providers struggle with costs as resources and staff levels can vary widely. AHIMA encourages CMS and ASTP/ONC to explore ways to support end-users with costs associated with adoption, updates, and use of these technologies, which can include, resources on best practices, and information on making the appropriate selections and purchases that are unique to each provider. Support should include resources and guidance for providers to use these technologies confidently and effectively to ensure the viability of quality data exchange.

AHIMA also recommends that CMS and ASTP/ONC, leveraging their oversight authority, seek to provide a predictable regulatory roadmap that enables both health IT vendors, health information networks, and end-users to understand their compliance obligations across various and sometimes competing agencies, while fostering participation in healthcare data sharing networks, including but not limited to the TEFCA.

AHIMA welcomes the ability to discuss with CMS and ASTP/ONC further opportunities to ensure the viability of data sharing networks.

Thank you for the opportunity to provide feedback to CMS and ASTP/ONC on how to improve the healthcare technology ecosystem through enhanced data quality in every facet of healthcare. AHIMA remains a committed partner to HHS in increasing availability of and access to health information through tailored and effective digital solutions. If AHIMA may provide any further information, or if there are any questions regarding this letter and its recommendations, please contact Andrew Tomlinson, Senior Director, Regulatory and International Affairs, AHIMA, at Andrew.Tomlinson@ahima.org.

Sincerely,

Lauren Riplinger, JD
Chief Public Policy & Impact Officer