Essentia Health

Executive Offices
502 East 2nd Street
Duluth, MN 55805
218.786.8975
EssentiaHealth.org

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The Honorable Dr. Mehmet Oz and Dr. Thomas Keane
Centers for Medicare & Medicaid Services
Assistant Secretary for Technology Policy
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: CMS-0042-NC
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via regulations.gov

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

Dear Administrator Oz and Assistant Secretary Keane:

On behalf of Essentia Health, we appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) and Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) Health Technology Ecosystem request for information (RFI). This RFI seeks input regarding the market of digital health products for Medicare beneficiaries as well as the current state of data interoperability, and the broader health technology infrastructure.

Overall, Essentia Health supports CMS's efforts to modernize the digital health ecosystem and emphasizes the need for streamlined, equitable, and interoperable solutions. **We strongly endorse initiatives such as TEFCA, digital signatures, and digital quality measures to reduce administrative burden and improve care coordination.** However, we are concerned about persistent challenges, including rigid billing structures, rural infrastructure gaps, third-party administrative complexity, and ambiguity in information blocking regulations. Clearer guidance and consistent standards are essential to ensure practical implementation and equitable access to digital health solutions across care settings.

Essentia Health is an integrated health system serving patients primarily in rural communities throughout Minnesota, North Dakota, and Wisconsin. Headquartered in Duluth, Minnesota, Essentia Health combines the strengths and talents of 15,000 employees, including 2,200 physicians and advanced practitioners, who serve our patients and communities through the mission of being called to make a healthy difference in people's lives. The organization lives out this mission with a patient-centered focus at 14 hospitals, 80 clinics, six long-term care facilities, three assisted and three independent living facilities, seven ambulance services, 29 retail pharmacies, and a rural health research institute. Over 84% of Essentia Health's service region is considered rural.

Background

The 21st Century Cures Act (2016) authorized CMS, ASTP/ONC, and NIST to implement policies expanding digital access to health data and ensuring patients have secure electronic access to their personal health information. In 2017, Executive Order 13813 directed federal agencies to improve patient access to healthcare data.

In 2020, CMS issued the Interoperability and Patient Access final rule, establishing standards for CMS-regulated payers to enhance data exchange and interoperability. That same year, ASTP/ONC released the ONC Cures Act final rule, which reinforced patients' no-cost access to electronic health information, including via third-party apps, and introduced a new certification criterion under the ONC Health IT Certification Program.

In 2024, CMS finalized the Interoperability and Prior Authorization Rule, requiring impacted payers to implement a Provider Access API. This API must make current claims and encounter data available to in-network or enrolled providers with an established treatment relationship, upon request.

CMS and ASTP/ONC are soliciting stakeholder input to inform potential future rulemaking aimed at improving health data exchange and fostering innovation in consumer digital health tools. Feedback is sought from a broad range of stakeholders, including patients, caregivers, providers, payers, health IT vendors, HIEs, clearinghouses, researchers, and developers, on the following:

- Elements of today's digital health ecosystem are working;
- Elements that are working inconsistently and need improvement;
- Elements that are impeding rapid progress; and
- Input for possible consideration in future rulemaking on policies to ease health data exchange and promote innovation in consumer digital health products, including how HHS can encourage patient, caregiver, and provider engagement with digital health products.

This RFI is organized into subsections with questions tailored to each respondent type. **Essentia Health is pleased to offer comments on the following categories:**

- Digital health apps;
- Data exchange;
- Digital identity; and
- Information blocking.

Digital Health Apps

CMS and ASTP/ONC are seeking stakeholder input on the role of digital health applications through the following targeted questions (PR-2, PR-4).

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?

Billing Flexibility for Digital Health Tools
Obstacles that hinder innovative applications include billing frameworks for Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM), and prescription digital therapeutics. These frameworks impose rigid and complex requirements that often hinder adoption and scalability and should be simplified. **CMS and ASTP/ONC should consider greater flexibility and provide clarity in billing codes and documentation requirements to support the broader integration of these tools into care delivery.**

Continuous Advancement to Electronic Forms and Signatures
The current reliance on physical signatures for various required forms introduces unnecessary delay and an administrative burden. Several examples of forms that currently require physical ("wet") signatures include utilization management forms, Ophthalmology Prescriptions, consent forms, CMS Appointment of Representative (form 1696), and the Advance Beneficiary Notice (ABN) forms.

Transitioning to secure digital signature workflows would enhance interoperability, reduce costs, and support broader adoption of digital health tools. CMS should prioritize policy updates that enable and standardize digital signature use across these and similar documentation processes. **We recommend that the agencies explore opportunities to digitize forms and allow for electronic signatures to decrease the administrative burden and streamline care delivery.** This should be the default standard while still allowing patients to request paper copies and hand signatures at their preference.

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?

Digital Health Equity and Infrastructure Access in Rural Areas
The most significant barrier to accessing digital health care is the lack of a permanent and stable federal regulatory framework around digital health. Patients should be able to access telemedicine from their home, and providers should be allowed to provide the service and be reimbursed accordingly. Ensuring equitable access to digital health services requires addressing disparities in broadband and cellular connectivity. Without reliable infrastructure, patients in underserved or rural areas may be excluded from tapping into the benefits of digital health innovation.

We recommend that the agencies establish a permanent and stable federal regulatory framework to support equitable access to digital health services. This framework should ensure that patients can receive telemedicine care from their homes and that providers are appropriately reimbursed. Additionally, addressing disparities in broadband and cellular infrastructure is essential to prevent the exclusion of rural and underserved populations from the benefits of digital health innovation.

Data Exchange

CMS and ASTP/ONC are inviting public comment on key issues related to data exchange within the digital health ecosystem through the following series of questions (PR-6, PR-7, PR-8).

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

Trusted Exchange Framework and Common Agreement (TEFCA)

TEFCA presents an opportunity to inaugurate a single, interoperable national framework. This consolidation would reduce redundancy, improve data consistency, and streamline governance. As a government-sponsored network, TEFCA has the promise of a single on-ramp for a broad range of healthcare providers and other actors to take part in nationwide data exchange. To ensure that its participants, including patients, can trust in the security and privacy of data exchange, TEFCA needs strong governance, including vetting and ongoing monitoring. **Essentia Health strongly supports the advancement of TEFCA towards a more unified and efficient health information exchange infrastructure**

To develop this further with real-world scenarios, TEFCA should include more purpose-built use cases addressing all facets of interoperability, while keeping patient care and treatment as the priority. Further public health use cases should be incorporated through TEFCA to help accelerate scalability to a nationwide adoption. In the future, TEFCA should encompass data exchange for purposes of Public Health, Payment and Operations, Government Benefits Determination, Individual Access, and more. From a public policy perspective, as consensus is developed around additional use cases, they should first be optional, then recommended, and subsequently required as adoption and familiarity increases.

To expand adoption and capabilities, the ASTP and CMS should expand the incentives available for TEFCA participation. For example, ASTP should designate TEFCA as an information blocking safe harbor through the TEFCA Manner Exception and provide bonus reimbursement to participating healthcare providers and payers.

State-based Health Information Networks/Exchanges

Health care providers, particularly health systems that operate in multiple states and serve border communities, continue to face challenges due to the variability and complexity of state-specific health information exchange systems. Furthermore, there have been numerous options to achieve digital health exchange, but with variability comes inconsistency and operational burden. For example, the current state-based health information exchanges add more bureaucracy than necessary especially as related to redundant information data feeds and sustaining security of PHI.

We applaud states for taking the initial lead on developing health information networks to advance health information exchange at a local and regional level. However, through the deployment of TEFCA, state health information networks join TEFCA or are phased out. A national strategy that standardizes provider data and exchange protocols integrated into EMRs would improve

interoperability, reduce costs, and support better care coordination. **We strongly recommend that the agencies adopt a national strategy to standardize health information exchange protocols and provider data formats across states.**

While state-led efforts have advanced local interoperability, the current patchwork of state-specific systems creates unnecessary complexity, particularly for multi-state health systems and border communities. Aligning state health information networks with TEFCA or phasing them into a unified national framework would reduce redundancy, enhance data security, and improve care coordination through consistent, integrated exchange standards.

Nationwide Provider Directory
Managing provider directories remains a persistent and costly challenge. This contributes to administrative inefficiencies, duplicative verification efforts, and poor data quality. These issues hinder interoperability, delay care coordination and payment, and create unnecessary burdens across the healthcare system. Fragmented, outdated, and inconsistent directories prevent seamless data exchange and undermine trust. Any provider directory needs to go beyond just FHIR endpoints.

A centralized data standard that supports a nationwide provider directory could enhance the efficiency of data exchange. There is an opportunity to reduce the administrative burden associated with maintaining multiple contracts with third-party vendors and eliminate duplicative efforts across states and organizations. **We recommend that the agencies consider establishing a centralized data standard to support the development of a nationwide provider directory.** This would streamline data exchange, reduce administrative burden associated with managing multiple third-party contracts, and eliminate duplicative efforts across states and organizations, ultimately enhancing interoperability and operational efficiency.

CMS must ensure the national provider directory replaces legacy systems rather than simply becoming one more source of data. This means establishing a unified, high-trust ecosystem where provider identity is managed centrally, operational data is sourced from organizations in context, and data standards evolve iteratively with real-world implementation. To that end, we offer the following recommendations and steps:

- **First, access and updates to the directory should be automated**. Machine-to-machine communication minimizes human error and burden while expediting updates, and it necessitates interoperable standards that all insurers and providers can follow. With automated updates to the directory, patients will receive timely electronic referrals sent to the appropriate in-network doctor at the correct location. The directory should include information on provider APM participation and digital technology capabilities. Additionally, there may be challenges if providers have multiple endpoints, as these would need to be identified for their specific purpose.
- **Secondly, the directory's automated data sources should be clear**. CMS should facilitate the creation of a unified directory for provider identity, such as name and National Provider Identifier (NPI). Other entities should be responsible for their relationship with that individual.

Healthcare providers should update contextual information, including location, contact details, and specialties. The responsibility should lie with the organization rather than the individual provider as currently practiced. Similarly, payers should monitor and revise which physicians are part of their network. Each entity should manage its own FHIR endpoints, including healthcare providers and payers.

- **Third, a national provider directory requires robust governance to ensure data quality**. The directory's data will be used to automate workflows that impact patient care and financial operations, making precision and accuracy essential. Without proper governance and validation, even a few poor-quality data entries can decrease trust and lead to system-wide inefficiencies. To avoid the shortcomings of previous directories, CMS should prioritize API-based, machine-readable data attestation over manual attestation through web portals or flat files.

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?

Data Transmission Between Health Plans and Providers

There is significant variability in how data is packaged and transmitted between payers and providers. This inconsistency creates inefficiencies and impedes interoperability. A standardized technical for digital information exchange would enhance coordination and reduce variability across the ecosystem. **We recommend that the agencies establish a standardized technical framework for digital information exchange between payers and providers.** The current variability in data packaging and transmission creates inefficiencies and hinders interoperability.

Administrative Burden from Intermediaries and Variable Payment Methods

The use of third-party intermediaries and disparate payment and data submission processes adds unnecessary administrative complexity. Streamlining these pathways—through unified standards and simplified workflows—would reduce provider burden and improve operational efficiency. Health insurance plans should simplify and move to a consistent form of payment method for services, reducing variability.

The practical challenge we face as providers working with third party vendors and intermediaries revolves around the transmission, storage, and use of information that was transmitted. For example, if a third party requests access to information, either through an API or other method, we are obligated to transmit information to the third party, who uses, stores, and may even profit off of information. However, the primary burden of sending information falls to providers and health care systems.

Designated Record Set Consistency

Designated record set (DRS) is the term used to define what information must be exchanged or made available to the patient. A "designated record set" (DRS) refers to a collection of health information, including medical and billing records, maintained by or for a covered entity (like a

healthcare provider or health plan) that are used to make decisions about individuals. However, the definition of DRS is very generic, meaning each organization or facility will have a different definition and therefore make available different information. This could further reduce the number of requests for the same information, reducing duplication.

We recommend that the agencies streamline administrative processes by establishing unified standards for payment and data submission, particularly in interactions involving third-party intermediaries. Furthermore, the DRS should be clarified and consistent with a standard definition, and providers should be able to charge fees for multiple requests for the same information. Additionally, policies should address the disproportionate responsibility placed on providers for transmitting data to third parties. A consistent, transparent framework would reduce complexity, protect patient data, and support more efficient care delivery.

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

Consistent Quality Reporting Standards
The lack of a standardized format requires continuous adaptation, diverting resources from patient care to administrative compliance. Establishing a consistent, long-term framework for quality reporting would reduce costs, improve data integrity, and enhance provider engagement. **We urge CMS to prioritize consistency in quality reporting formats.** Frequent annual changes to reporting structures and methodologies create significant operational and financial burdens for healthcare providers.

As a provider and Value-Based Care (VBC) organization, we are also responding to RFI question VB-2 regarding the integration of key technologies, such as AI, population health analytics, risk stratification, and digital quality measurement, into APM requirements. We see significant opportunities to streamline CMS quality reporting programs. Current variability in submission methods across quality reporting programs (QRPs) and the Medicare Shared Savings Program (MSSP) creates administrative burden.

While electronic clinical quality measures (eCQMs) have advanced standardization, we encourage CMS to accelerate the transition to digital quality measures (dQMs), which leverage interoperable data sources and are fully computable. CMS defines digital quality measures (dQMs) as quality measures that use standardized digital data from one or more sources of health information that are captured and exchanged via interoperable systems; apply quality measure specifications that are standards-based and use code packages.

The CY 2025 Physician Fee Schedule (PFS) Final Rule sunset the Web Interface Portal and requires digital quality measures reporting. This transition creates significant challenges, as the policy does not consider the technical capabilities of smaller practices. Reporting electronic clinical quality measures (eCQMs) requires all practices in an ACO to generate certain types of files, like QRDA files, through their EHRs.

While the transition to eCQMs is well-intended, we encourage CMS to propose short- and long-term solutions in the CY 2026 PFS Proposed Rule. In the short-term, CMS should provide flexibility for ACOs to exclude reporting on patients whose records are not stored in QRDA-capable EHRs, so long as CMS' overall reporting requirements are met (i.e., reporting data on 75% of an ACO's patients). This will allow ACOs to provide quality measures for most of their patients while exempting smaller practices within the ACO that do not have the capacity to report.

A phased approach with robust testing and pilot programs would reduce provider burden, enhance data quality and interoperability, and improve alignment with value-based care goals. **Essentia encourages CMS and ASTP/ONC to consider future digital quality measurement (dQM) goals and how they work to further the goal of quality improvement, relying less on eCQMs.**

Information Blocking

CMS and ASTP/ONC are seeking stakeholder perspectives on the current challenges and potential opportunities associated with 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?

Complexity of Information Blocking Regulations

We believe in the importance of making critical health information available to patients, the clinicians treating those patients, and those with appropriate reasons for having access, among which are payment, care oversight and research. The current information blocking regulatory framework continues to present challenges in interpretation and implementation. There is a need for greater clarity and potential refinement of the rules to ensure they are practical and aligned with real-world clinical workflows.

- The 21st Century Cures Act delegated to the Department of Health and Human Services (HHS) authority to identify reasonable and necessary activities that do not constitute information blocking. ASTP should fulfill this obligation by providing clear pathways for good information sharing.
- An increase in enforcement through more complaints creates a perverse environment that is focused on legal requirements rather than achieving the end goals of good information sharing.
- ASTP should have a clear roadmap that provides actors regulatory certainty on how they can be good information sharers and avoid information blocking. As an example, ASTP should expand the TEFCA Manner Exception to apply when a fulfiller makes information available through the framework, regardless of whether the requestor participates in TEFCA.

As more data elements are added to the USCDI, how those elements interact with information blocking regulations is a moving target. In other words, when updates are made to USCDI, the elements should consider the interaction with information blocking regulations for a more seamless integration into practice. Additionally, the processes by which the Office of the Inspector General will determine if information blocking has occurred are ambiguous, including the appeals process.

At this time, we do not recommend making substantial changes to the information blocking regulations, but continued education, definition of a standard national designated record set, and use cases and examples would be most helpful to ensure compliance. However, the disincentive structure in the current rule is excessive.

Some areas of clarity would improve the information blocking regulations pertaining to exceptions. For example, we have clinical cases that are very complex and interact with several different data systems across several health care providers. We have received numerous requests for information on the same complex case that we have repeatedly provided. While it may seem a simple request, in fact, requires resources to review the specific request to ensure the information is provided. Therefore, **we would like to see an exception established to refuse providing the same information repeatedly to the same requester.** The agency should explore an exception that would protect health care providers that good faith effort is made to fulfill a request without fear of information blocking with reasonable limits on the number of requests.

Conclusion

On behalf of Essentia Health, we appreciate the opportunity to provide comments on the Health Information Technology (ONC) Health Technology Ecosystem RFI. Essentia Health recognizes the importance of opportunities to contribute to the dialogue on modernizing the digital health ecosystem. We urge the agencies' attention to persistent challenges in this space, including the need for a stable federal regulatory framework for digital health, disparities in rural broadband infrastructure, variability in data exchange standards, and the complexity of information blocking regulations.

Addressing these concerns through consistent policies, streamlined workflows, and enhanced provider support will be critical to realizing the full potential of digital health innovation and access across the communities we are privileged to serve.

Please feel free to contact me with any questions.

Sincerely,

Brian Vamstad, PhD
Director of Regulatory Affairs
Essentia Health
brian.vamstad@essentiahealth.org