

June 16, 2025

Centers for Medicare & Medicaid Services (CMS), Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

Submitted electronically at: https://www.federalregister.gov/documents/2025/05/16/2025-08701/request-for-information-health-technology-ecosystem

Attention: Request for Information (RFI); Health Information Ecosystem [CMS-0042-NC]

To CMS and ASTP/ONC:

Thank you for the opportunity to respond to the Health Technology Ecosystem RFI. The Minnesota e-Health Initiative (Initiative) is pleased to submit comments as a public-private collaborative focused on advancing the adoption and use of electronic health records and other health information technology, including health information exchange. A legislatively authorized 25-member advisory committee guides the Initiative. Review Appendix A for list of advisory committee members. The Minnesota Department of Health, Center for Health Information Policy and Transformation, coordinates activities of the Initiative.

The advisory committee applauds the collaboration between CMS and ASTP/ONC and encourages ongoing collaboration between these two federal entities. The questions of this RFI are very important. For future input opportunities, we request additional time to work with our partners to provide a thorough response.

As action is taken to advance interoperability, improve data access, and support care coordination including referrals and prior authorizations, it is necessary to consider the needs of and provide technical assistance and funding to

- small and rural providers;
- providers across the care continuum including but not limited to pharmacy, long-term and post-acute care, home health care, and behavioral health; and
- local, state, and federal public health, human services, and social service agencies.

Artificial intelligence (AI), particularly generative AI and large language models, needs ongoing development, oversight and certification for use in health and public health. Governance and guidance are needed to assure AI is used to improve health and healthcare for patients and communities, reduce workforce burnout, and allow efficiencies to address ongoing shortages in our healthcare workforce. Governance is needed to address the risk, consent, and legal considerations and limit data bias. The recently released An Artificial Intelligence

Code of Conduct for Health and Medicine: Essential Guidance for Aligned Action¹ has a set of rules – guideposts for development and use of Al. These rules focus on ensuring equity, improving the workforce, monitoring performance, and more. ONC and CMS should build off this work and support the governance of Al for health and public health.

We also support the University of Minnesota's Response to a Request for Information on the Development of a 2025 National Artificial Intelligence (AI) Research and Development (R&D) Strategic Plan². Academia plays a key role in workforce development and upskilling, shaping the future of responsible AI development, and strengthening data science.

Another need is education – for providers and organizations as well as patients and caregivers. Gaps in digital health and technology literacy will limit the benefits of improved interoperability and data access. Specific areas needing ongoing education include artificial intelligence, information blocking, privacy and consent, patient monitoring devices, and health management and care apps.

Please consider the following comments related to the Health Information Ecosystem RFI. They are developed with input from across Minnesota and from ongoing and previous work of the Initiative. Contact Kari Guida, Senior Health Informatician, Center for Health Information Policy and Transformation, Minnesota Department of Health at kari.guida@state.mn.use with any questions.

Sincerely,

The Minnesota e-Health Advisory Committee Co-Chairs

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¹National Academy of Medicine. 2025. *An Artificial Intelligence Code of Conduct for Health and Medicine: Essential Guidance for Aligned Action*. Washington, DC: The National Academies Press. https://doi.org/10.17226/29087. ²Data Science and Al Hub, University of Minnesota. https://dsai-hub.umn.edu/news/data-science-and-ai-hub-has-responded-white-house.

Minnesota e-Health Initiative Coordinated Response

Patients and Caregivers

PC-1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs, as well as the actions you should take?

An app that combined notes or actions from multiple providers in one summary document and helps organize personalized advice into a care plan.

PC -1 a. What are the top things you would like to be able to do for you or your loved ones' health that can be enabled by digital health products?

An app that can manage prescriptions and appointments across providers and systems. This can already happen with a provider portal but not across providers.

PC-4 a. What apps should exist but do not yet? Why do you believe they do not exist yet?

A personal health coach app that summarizes all the advice and information a patient receives from any provider and helps them create their own plan for how to care for themselves.

An app that centralizes all patient health records across the lifespan regardless of where in the US the care was received. It needs to include childhood and adult immunizations and allows for patients to contribute information from home monitoring equipment.

PC–5 a. What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?

Leveraging current testing and certification programs from the FDA or ONC. An example is the Certified Health IT Product List (CHPL) is a comprehensive and authoritative listing of all certified health information technology that have been successfully tested and certified by the ONC Health IT Certification program.

PC–11 d. What is the ongoing role of HIEs amidst other entities facilitating data exchange and broader frameworks for data exchange (for example, vendor health information networks, TEFCA, private exchange networks, etc.)?

A problem to address is if the vendor doing the exchanging (e.g., digital therapeutics vendor/developer on an App), how does that data get enumerated as vendors do not have an NPI.

Providers

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?

- Provide education to providers on apps and ongoing monitoring to improve health outcomes.
- Provide education on codes for reimbursement for providers and organizations for education and monitoring of apps and reviewing associated data from apps.
- Subsidize the implementation of digital health products and connections to HIOs and other HIE providers.
- Address broadband disparities.
- Provide digital health and health technology literacy education materials to providers for patients written in plain language.

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

Follow the example of Open Notes in sharing information with patients. Be sure to include recommendations and/or requirements for making information understandable and available in multiple languages and in plain language.

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: Current billing frameworks for eConsults, Remote Patient Monitoring (RPM), Remote Therapeutic Monitoring (RTM), and prescription digital therapeutics impose rigid and complex requirements. These standards often hinder adoption and scalability and should be simplified. Greater flexibility and clarity in billing codes and documentation requirements would support the broader integration of these tools into care delivery.

Continuous Advancement to Electronic Forms and Signatures: We recommend CMS explore opportunities to digitize forms and allow for electronic signatures to decrease 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. There are several forms that currently require physical ("wet") signatures, including utilization management forms, Ophthalmology Prescriptions, consent forms, 1696 CMS Appointment of Representative, and the Advance Beneficiary Notice (ABN) forms.

The current reliance on physical signatures introduces unnecessary delays and an administrative burden. Transitioning to secure digital signature workflows would enhance interoperability, reduce costs, and support broader adoption of digital health tools. We encourage CMS to prioritize policy updates that enable and standardize digital signature use across these and similar documentation 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?

It is very important. However, the push should be for reducing the volume of documents with unstructured data, making entry of structured data more efficient, and using AI tools to make unstructured data more structured to allow better interoperability.

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 access for 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. Making the digital health changes permanent will avoid all the inefficiencies and anxiety each deadline causes for patients and care providers.

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 the benefits of digital health innovation.

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

Some partners strongly support the advancement of the Trusted Exchange Framework and Common Agreement (TEFCA) towards a more unified and efficient health information exchange infrastructure. TEFCA presents an opportunity to inaugurate a single, interoperable national framework. This consolidation could reduce redundancy, improve data consistency, and streamline governance. Some support building further public health use cases through TEFCA to help accelerate TEFCA and its' scalability to nationwide adoption.

PR-6 a. Please provide specific examples.

State 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.

PR-6 b. What changes would you suggest?

Some partners applaud states taking the initial lead on developing health information networks to advance health information exchange at a local and regional level and think through the deployment of TEFCA, state health information networks should be phased out. A national strategy that standardizes provider data and exchange protocols integrated into EHRs could improve interoperability, reduce costs, and support better care coordination. CMS and ONC are encouraged to prioritize these initiatives as part of its broader digital health modernization strategy.

Some partners strongly support leveraging TEFCA and QHINs to standardize national and state public health reporting for things like syndromic surveillance: Having deidentified data exchanges between QHIN's and

public health could allow for more timely syndromic surveillance to address things like infectious disease outbreaks or drug overdose patterns.

Nationwide Provider Directory: 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.

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?

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.

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 could 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 from the information. However, the primary burden of sending information falls to providers and health care systems.

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

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.

We urge CMS to consider how to optimize redundant reporting requests from the national and state levels and overall reduce reporting requirements when data is already available from QHIN's or other sources.

PR–8 c. 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?

HHS should consider future digital quality measurement (dQM) goals and how they work to further the goal of quality improvement, relying less on eCQMs. 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. Furthermore, dQMs are computable in an integrated environment without additional effort. Transitioning to dQMs through robust testing and pilot deployment could substantially reduce administrative burdens for providers through increased automation, standardized language and format, improved data quality, and enhanced interoperability.

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

Patients/individuals need clear information about what they are opting in to or other means to discern consent (e.g., individuals did not necessarily understand what they were consenting to for 23andMe). Also, some states have laws beyond HIPAA. CMS and ONC need to consider the role of a consent API in all situations — at all levels of regulation.

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

Patients/individuals need clear information about what they are opting in to or other means to discern consent (e.g., individuals did not necessarily understand what they were consenting to for 23andMe).

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?

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. 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.

At this time, the focus should be on continued education and use cases and examples would be most helpful to ensure compliance. In addition, improved clarity on the processes by which the Office of the Inspector General determines if information blocking has occurred, including the appeals process, are needed.

Payors

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?

The potentially low ROI of participating in TEFCA through a QHIN may be a barrier to entry for very small health plans. With no guarantee that the largest providers in our network will agree to exchange data at an affordable cost, the potential burden reduction may be too small to justify the expense.

Also, how state laws interplay with TEFCA is an uncertainty and can limit participation.

PA—3. How can CMS encourage payers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins?

Consider including digital identity credentials as part of the ONC Health IT Certification Program.

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

A nationwide provider directory with a limited data set with FHIR endpoints and digital identity credentials would streamline exchange significantly. The current system of collecting provider data is fragmented, requiring Minnesota payers to obtain provider data from multiple sources (delegate provider files, the Minnesota Credentialing Collaborative, and proprietary provider application systems). A nationwide provider directory would allow providers to update information in a single place, improving data quality and reducing administrative burden on providers. Payers would benefit from improved data accuracy and process simplification. Payers would benefit from FHIR endpoints because they offer automated, near real-time data exchange. This could reduce administrative burden on payers. Provider data management software and SaaS vendors could build against the standard FHIR endpoints, allowing their systems to be compatible with the nationwide provider directory. If a nationwide provider directory with FHIR endpoints is widely adopted, most provider data management vendors would have a strong incentive to use it, benefiting all their health plan customers. The use of digital identity credentials (e.g., Login.gov, ID.me) could enhance security and trust in provider and partner interactions. It could also reduce reliance on proprietary login systems, which can be inconsistent, costly to maintain, and increase password fatigue. Federated identity management is more scalable and secure than disparate proprietary login systems.

PA-5. What are ways payers can help with simplifying clinical quality data responsibilities of providers?

Payers, including CMS, could propose a baseline of quality measures they all would use and only add others if necessary.

PA—5 a. How interested are payers and providers in EHR technology advances that enable bulk extraction of clinical quality data from EHRs to payers to allow them to do the calculations instead of the provider-side technology?

Some payors are interested in being able to bulk extract clinical quality data from our providers' EHRs. Chartchases are slow and burdensome. PA—5 b. In what ways can the interoperability and quality reporting responsibilities of providers to both CMS and other payers be consolidated so investments can be dually purposed? Are there technologies payers might leverage that would support access to real time quality data for healthcare providers to inform clinical care in addition to simplifying reporting processes?

CMS could propose a floor that all payers would use.

PA-7. How can CMS encourage payers 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?

Encouraging more payers to submit information blocking complaints could have both positive and negative consequences. Payers are well positioned to detect information blocking from providers and their complaints could help identify systemic issues, leading to improved compliance and interoperability. However, more complaints could erode trust between payers and providers. Alternative approaches might be for CMS to provide additional stakeholder education to clarify what constitutes information blocking or increasing transparency via scorecards to highlight good actors.

Technology Vendors, Data Providers, and Networks

TD-1. What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?

- Expand funding and incentives grant programs, innovation challenges, or payment models that directly reward entities for tools created to serve the Medicare population.
- Streamline regulatory guidance simplifying compliance around HIPAA, interoperability like TEFCA and FHIR, and Medicare reimbursement policies
- Enhance data access and APIs expand Blue Button 2.0 to ensure more real-time data is available
- Encourage public-private partnerships and collaboration HIEs, HDUs, research institutes, tech firms will foster innovation

TD-2. Regarding CMS Data, to stimulate developer interest—

CMS data sets can drive innovation in healthcare solutions in predictive analytics to care coordination, this could be done by standardized APIs and could provide opportunities to enhance care delivery based on analytics and care coordination opportunities.

TD-2 a. What additional data would be most valuable if made available through CMS APIs?

Some considerations:

Social indicators related to health – housing status, food security, transportation access, employment factors – this information could impact risk stratification models which can lead to targeted interventions and resource allocation to targeted populations.

- Real time claims and utilization data claims processing, adjudication details and real time patient
 encounters will support predictive analytics in waste detection, estimation of potential costs and
 efficiencies.
- Prescription medication and adherence information refill rates, patterns and utilization trends will enable meds management solutions.
- Patient Reported Outcomes and Experience could lead to quality-of-care improvements and patient reported health measures.
- Provider level performance and value-based care metrics provider utilization patterns, referral networks, and comparative quality benchmarks, technology could create decision support tools that are embedded into the HIE technology for leverage by the physicians, payers, and healthcare leaders.
- Advancing population health insights real-time chronic disease trends, hospitalization patterns, infectious disease outbreak information, deidentified drug overdose information, and regional health indicators will empower public health with predictive modeling.

TD-2b. What data sources are most valuable alongside the data available through the Blue Button 2.0 API?

EHR and clinical data, social indicator data, prescription drug and pharmacy utilization data, HIE/HDU and other interoperability network data. Other sources included wearable and patient generated data and Medicare advantage and alternative payment model data.

TD-2 c. What obstacles prevent accessing these data sources today?

Inconsistent data interoperability and standards, data quality and standardization issues, strong data governance modeling and privacy regulations, organizational and stakeholder resistance, and technical or infrastructure limitations.

TD-2 d. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers?

- Social indicator data
- Real time claims and utilization
- Ability for patients to report outcomes/patient generated data
- Prescription drug and pharmacy
- Behavioral and mental health
- Interoperability and cross system API (FHIR based expansion) related to care transitions, referral networks, and cross provider coordination
- Al-Assisted clinical decision support related to risk predictions, evidence-based treatment recommendations, and machine learning assisted diagnostics

TD-3 a. What are the challenges and benefits?

Standardization remains the largest issue in digital identity implementation. We can create a unique patient identifier, but this is not a national identifier with a standardized format to be supported within other states to help with patient matching. Not having a standard identifier causes challenges to match a patient between systems resulting in inefficiencies and potential for inaccurate matching causing patient safety issues.

Other challenges are privacy and security, fraud and identity theft risks, user experience and adoption barriers for patients and providers with authentication complexity and low digital literacy among Medicare populations which may require alternative considerations.

Benefits are enhanced security and fraud preventions with relation to any biometric authentication, seamless access and interoperability, better patient engagement and convenience, support of value-based care and population health especially within high-risk populations.

TD-3 b. How would requiring digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800–63–3 IAL2/AAL2 CSPs) impact cybersecurity and data exchange?

Identity credentials can strengthen cybersecurity by reducing fraud and unauthorized access, ensuring verified users can access health data. For exchange of data, it can improve trust and interoperability, making cross system sharing more secure and efficient.

TD-3 c. What impact would mandatory use of the OpenID Connect identity protocol have?

This would standardize identity verification across healthcare systems. While making the exchange safer and more efficient, the negative impacts could be high integration costs, provider adoption hurdles, and accessibility for all users.

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

CMS can encourage adoption by mandating interoperability, providing financial incentives for standardized APIs, enhance developer support with clear documentation, environments for testing and technical assistance that can support stakeholders quickly, finally by partnering with the industry to drive adoption through trusted networks.

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?

CMS, ONC or a trusted public-private entity could maintain and publish a provider directory for accuracy and accessibility while leveraging HIE. Incentive to leverage the system can be free, while advanced features could have a subscription model. Advanced features could be API integration and custom data feeds, analytics and insights, enhanced security and compliance tools, automated credentialing and provider verification (within the HIE), priority support and custom implementation assistance.

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

TEFCA attempts to standardize interoperability by creating a unified trusted framework, cross network connectivity, ensures HIPAA compliant and secure transfer of health records, and provides nationwide access. TD–6 a. What existing alternatives should be considered?

Alternatives include FHIR, USCDI, CommonWell, CareQuality, and public health data initiatives which include leveraging state and regional HIEs.

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

Standardization of key health data elements within USCDI can make data exchange more consistent across systems, ensures better patient matching, smoother transitions of care and more structured health information sharing.

The limitations are slow adoptions, limited data scope (not including any social indicator data), and integration challenges with older systems. In addition, the recent removals of and changes to patient demographic and health data elements limits that value of data and can harm individuals and communities.

TD-7 a. Does it contain the full extent of data elements you need?

The recent removals of and changes to patient demographic and health data elements limits that value of data and can harm individuals and communities.

TD-7 b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized?

Limitations in the definition, like lacking social determinants data, claims data, etc.

TD-7 c. If so, would adding more data elements to USCDI add value or create scoping challenges? How could such challenges be addressed?

Yes, scoping challenges could create complexities in implementation, adoption delays and data governance concerns. Challenges can be mitigated by a phased adoption approach, clear validation rules and industry collaboration (consortium driving the results), technical support and incentives

TD-7 d. Given improvements in language models, would you prefer a nonproprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?

A non-proprietary, less structured format could improve data coverage but would require more processing for accurate interpretations. Depending on the goals, impacts the solution, if efficiency and standardization matter more, structured formats would be preferable, but if flexibility and broad accessibility are the priority, then less structure.

TD-8. What are the most effective certification criteria and standards under the ONC Health IT Certification Program?

USCDI, FHIR APIs, Clinical Decision Support, Security and Privacy Standards, ePrescribing and meds management.

TD-9 a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?

The benefits are improved functionality, enhanced flexibility for providers leveraging tools without replacing or updating entire systems, and acceleration of innovation to build modern and scalable solutions.

TD-9 b. What would be the drawbacks?

Security risks, integrations challenges, data silos, cost and complexity.

TD-9 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)?

Mandating full API support for all patient data types (fax, free text, structured data), standardizing requirements, enforce interoperability rules, and providing incentives to all providers across the care continuum.

TD-9 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?

Reimbursement for data completeness and collaboration, mandate interoperability compliance, streamline reporting requirements, and provide technical support and resources to all providers across the care continuum.

TD-9 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?

EHRS can be used, but leveraging the HIE would be more successful for bulk data export, automated quality measure calculations and secure data exchange. Concerns with this approach are consistent with the other concerns mentioned above, there are data privacy risks, integration challenges, and standardization issues with consistent data formats.

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?

Full data access, standardized API functionality, enhance security and privacy controls, enforce interoperability compliance, and provide technical guidance and acceptance incentives.

TD-11 a. Should this capability be revised to specify standardized API requirements for EHI export?

Yes, this could improve consistency, interoperability and usability.

TD-11 b. Are there specific workflow aspects that could be improved?

Yes, for the HIE – direct EHR integration, standardized data formats, automated data retrieval, improved user experiences, and deidentified data specific APIs for reporting or public health

TD-11 c. Should CMS consider policy changes to support this capability's use?

If CMS does, incentives and technical assistance for all partners and providers across the care continuum.

TD–12. Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?

Potentially but only if clear quality and interoperability requirements as well as security standards are met.

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

Better care coordination, advanced analytics, improved patient engagement, development of patient digital health coaches that help them navigate their own data, and streamlined research and innovation.

TD-13 a. What are the primary obstacles to this?

Interoperability inconsistencies, provider adoption, security and privacy concerns with HIPAA compliance, and third-party app delays.

TD-13 b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?

USCDI is standardized, structured and fairly easy to adopt, but it has limited data. Full EHI has comprehensive access that supports AI insights but it is harder to process and therefore standardize

TD-14 a. How many endpoints is your network connected to for patient data sharing? What types, categories, geographies of endpoints do you cover? Are they searchable by National Provider Identifier (NPI) or organizational ID?

Koble-MN is connected to 25 unique endpoints that represent 130 hospitals in Minnesota. These endpoints are searchable by OID in the eHealth Exchange.

TD-14 b. How are these connections established (for example, FHIR (g)(10) endpoints, TEFCA/Integrating the Health Enterprise (IHE) XCA, or proprietary APIs)?

These endpoints are connected via VPN and data is gathered via HL7 2.x messages from these hospital sites.

TD–14 c. Do you interconnect with other networks? Under what frameworks (for example, TEFCA, private agreements)?

Koble-MN is connected directly to eHealth Exchange and CareQuality via DURSA.

TD-15 a. How would increased use of bulk FHIR improve use cases and data flow?

Faster data retrieval, supports population health, and enhances interoperability.

TD-15 b. What are the potential disadvantages of their use?

Security risks, processing challenges, interoperability issues (inconsistencies), and data governance.

TD-16. What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?

Point to point is dedicated, secure, quicker, but its costly and not as scalable. Shared network proves to be much more scalable and cost effective but there can be higher latency

TD-16 a. Do current rules encourage scalable network participation?

The challenges that still exist include interoperability gaps, security and compliance burdens slowing the adoption of scalable solutions, and cost constraints.

TD-16 b. What changes would improve alignment (for example, API unification, reciprocal access)?

Standardized requirements, interoperability incentives, security and compliance updates, clear governance frameworks

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?

CMS and ASTP/ONC should continue to play a role of guidance and limited oversight of networks to ensure a level playing field and shared standards and expectations. Funding infrastructure improvements, standardizing data exchange, encouraging provider participation, and monitoring network effectiveness (usage, outcomes, adoption) are additional roles.

TD-19 b. Which workflows would benefit most from functional price transparency?

Workflows involving patient access and referrals.

Value-Based Care Organizations

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?

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.

There are numerous opportunities to simplify and streamline quality reporting programs. Currently, across all CMS quality reporting programs (QRPs) and the Medicare Shared Savings Program (MSSP), hospitals and providers are required to submit quality measures. The mechanism for submitting the required data varies. However, a common reporting method that continues to grow are mandates around electronic clinical quality measures (eCQMs). eCQMs are defined by CMS as measures specified in a standard electronic format that use data electronically extracted from electronic health records (EHR) and/or health information technology (IT) systems to measure the quality of health care provided.

HHS should consider future digital quality measurement (dQM) goals and how they work to further the goal of quality improvement, relying less on eCQMs. 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. Furthermore, dQMs are computable in an integrated environment without additional effort. Transitioning to dQMs through robust testing and pilot deployment would substantially reduce administrative burdens for providers through increased automation, standardized language and format, improved data quality, and enhanced interoperability.

Artificial intelligence has the opportunity to transform health care delivery to address staff shortages, improve data summarization, and allow patients to more easily navigate the health system and have individualized care. It also brings many risks and will need a robust governance framework to make sure the most useful and safe Al tools are selected and used to improve overall health and wellbeing.

Improved care coordination has the opportunity to improve patient care, reduce cost of care, and allow better integration of the many entities responsible for the care of an individual person.

VB-3. What are essential health IT capabilities for value-based care arrangements?

ADTs and ability to exchange clinical information to augment claims data.

VB—15. How could a nationwide provider directory of FHIR endpoints help improve access to patient data and understanding of claims data sources? What key data elements would be necessary in a nationwide FHIR endpoints directory to maximize its effectiveness?

A national provider directory of FHIR endpoints would be very valuable. It should include all providers – across the care continuum.

Appendix A

Minnesota e-Health Initiative Advisory Committee Members

Co-Chairs

Bryan Jarabek, MD, PhD, Chief Medical Informatics Officer, M Health Fairview

Representing: Large Hospitals

Lindsey Sand, LHSE, NHA, Vice President of Population Health, Vivie

Representing: Health Care Administrators

Members

Najma Abdullahi, Executive Board of Directors-Member, UMN Community-University Health Care Center

Representing: Consumer Members

Stacie Christensen, Deputy Commissioner and General Counsel

Representing: Department of Administration

Brittney Dahlin, MS, RHIA, CPHQ, Chief Operating Officer, Director of Quality Improvement, Minnesota

Association of Community Health Centers

Representing: Community Clinics/Fed Qual. Health Centers

Greg Hanley, MBA, FACHE, CPHQ, Vice President, Health Services Quality and Operations, UCare

Representing: Health Plans

Kim Heckmann, MSN, FNP-C, SCRN, PHN, Primary Care NP Residency Program Director and APRN Educator, VA

Medical Center

Representing: Nurses

Matt Hoenck, Director of IT & Analytics, South Country Health Alliance

Representing: Health Plans

Nila Hines, Chief Data and Analytics Officer

Representing: Minnesota Department of Health

Steve Johnson, PhD, Associate Director, CTSI Health Informatics Program, University of Minnesota

Representing: HIT Training and Education

Mark Jurkovich, DDS, MBA, MHI, Director of Data Infrastructure, Health Care Systems Research Network

Representing: Dentistry

George Klauser, Executive Director – Community Services-ACO/Healthcare Consultant, Lutheran Social Services

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Representing: Social Services

Lisa Klotzbach, MA, BA, PHN, Public Health Supervisor – Informatics, Dakota County Public Health

Representing: Local Public Health

Sarah Manney, DO, FAAP, Chief Medical Information Officer, Essentia Health

Representing: Physicians

Genevieve Melton-Meaux, MD, PhD, Senior Associate Dean, Health Informatics and Data Science, University of

Minnesota

Representing: Academics and Clinical Research

Lisa Moon, PhD, RN, LHIT, LNC, CEO, Principal Consultant, Advocate Consulting, LLC

Representing: Experts in Health IT

Jane Pederson, MD, MS, Chief Medical Quality Officer, Stratis Health

Representing: Experts in Quality Improvement

Charles Peterson, Chief Executive Officer, The Koble Group

Representing: Health IT Vendors

Peter Schuna, Chief Executive Officer, Pathway Health Services

Representing: Long Term and Post-Acute Care

Ashley Setala, Director of Regulation & Policy Strategy

Representing: Department of Commerce

Mathew Spaan, Manager, Care Delivery and Payment Reform

Representing: Department of Human Services

Tarek Tomes, Commissioner

Representing: MNIT

Laura Unverzagt, MBA, Vice Chair-Information Technology, Mayo Clinic

Representing: Health System CIOs

Mary Winter, Senior EDI Analyst, PrimeWest Health Representing: Health Care Purchasers and Employers

Designated Alternates

Alexandra De Kesel Lofthus, Associate Director, State Strategy, Unite Us

Representing: Consumer Members

Alicia Jackson, MS, CPPM, Healthcare Analyst Principal, Blue Cross Blue Shield of Minnesota

Representing: Health Plans

Roxanee Pierre, MD, MHA, Medical Director/ Administrator, Eden Pathways Homecare Agency

Representing: Physicians

Adam Stone, Vice President Services Delivery, Chief Privacy Officer, Secure Digital Solutions, Inc.

Representing: Experts in Health IT

Tamara Winden, PhD, MBA, FHIMSS, FAMIA, Founder Principal Consultant, Winden Consulting, LLC

Representing: Academics and Clinical Research