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June 16, 2025

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-0042-NC
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Sir or Madam,

Oracle Health, a leading supplier of electronic health records and clinical and revenue cycle information systems appreciates the opportunity to submit comments in response to the *Request for Information; Health Technology Ecosystem.*

Oracle Health hopes these comments will be of value to CMS and ASTP/ONC in considering possible updates to the regulation impacting the health technology ecosystem. Any references to product capabilities in the following letter is intended to outline our general product direction. It is intended for informational purposes only and is not a commitment to deliver any material, code, or functionality. The development, release, and timing of any features or functionality described for Oracle's products remains at the sole discretion of Oracle.

We are happy to provide further information about any of the following comments.

Sincerely.

Stacy Amin
Chief Counsel for Global Health Regulatory and Policy
Oracle Health

Executive Summary and General Comments

We greatly appreciate the opportunity to provide our thoughts and insights on the multitude of challenges and opportunities that present themselves across the healthcare technology ecosystem. Throughout this letter we identify challenges that impact all stakeholders across the healthcare ecosystem, challenges that may be unique to each stakeholder group, and, when we can, solutions and opportunities to address those challenges.

Common challenges that we will highlight throughout the comment letter include:

- **Longitudinal Health Records.** The healthcare system experiences significant difficulties in compiling a complete, longitudinal view of the patient's health history. While the ASTP/ONC certification of health IT program has led the way for interoperable exchange of information across providers and to patients, there are still gaps in the availability of standardized data and the necessary health IT products and infrastructure among certain provider types or specialty areas of care. Additionally, there is a need to focus on moving bulk sets of data across systems.

- **Incentives for Preventive Care.** Most healthcare within the U.S. is paid for on a Fee-For-Service (FFS) basis or on a limited Value-Based Care (VBC) basis incorporating a quality reporting requirement. Provider participation in value-based care has not scaled in part due to the complexity of obtaining real-time data. Providers need to understand their performance against potential value-based care contracts and be able to obtain real-time patient data in order to manage care effectively for their patients. Access to real-time data can help prevent hospitalization, re-admissions, and allow providers to provide care that promotes health and prevents disease.

- **Patient Access to Data.** Patients' behavior constantly impacts their health whereas providers only have irregular opportunities to impact their patients' health. Patients want to take control of their own care and want assistance in understanding their healthcare information to inform them of the next steps in their healthcare journey. We need to incentivize the use of technology that will give patients 1) seamless access to their complete patient record without the need for multiple logins and portals, and 2) insights into their health and health care journey. Clinicians, caregivers, and others impacting patient care need to focus on the patient's health between clinical encounters, including an understanding of social determinants of health.

Most patients' healthcare information is contained in disparate patient portals and health systems and the burden to compile that data largely falls to the patient and/or caregiver. Even when patients can get their data, they continue to face accessibility and usability challenges. The lack of access, ownership, and control of digital health data has caused patients significant frustration and created an environment where patients and clinicians are forced to make health decisions without the full picture, causing overall dissatisfaction, as well as an increased risk for poor health outcomes.

- **Transparency for Healthcare Price and Quality.** Patients need healthcare price and quality transparency in advance of receiving services. There are requirements in place for hospitals and certain payers to publish their pricing information. However, that information is still difficult for many patients to understand and may not give a complete picture of the actual out of pocket impact a set of care will have on a patient. This is largely the result of an incomplete picture of what care is needed, what care is covered, and what the current state of out-of-pocket expenses are for an individual patient. Quality data is also found on yet another myriad of websites and patients have difficulty in putting together both cost and quality information to make informed decisions.

- **Privacy and Patient Consent.** Restrictions within the statutory and regulatory framework related to privacy and the patient's ability to consent to share their data or not. Laws and regulations across the federal, state, and tribal level, impact the healthcare ecosystem, as well as the variety of data for which patient consent must be considered before information can be shared for primary and secondary purposes. Patients should be empowered with the ability to determine how and where to share their data – including with non-traditional third parties such as loved ones, friends, and clinicians of their choosing. Patients, providers, payers, and health IT developers must navigate this complex web of requirements while many also must balance considerations related to compliance with information blocking. This may lead to unintended over-sharing and consequently substantial under-sharing compared to what is authorized to be shared. Health systems are making decisions for their patients, and patients are not able to make decisions about where their data goes, or to be able to provide their data for clinical trial matching, or for research.

- **Regulatory Clarity**. The provider shortage in the U.S. poses a daily threat to the ability to provide high quality accessible care to patients. The aging population, along with the increasing demand for services, is putting incredible strain on the provider workforce. Technology exists today to transform the way clinicians practice medicine, navigating large amounts of data for providers and surfacing real-time care insights and best practices, identifying care gaps, and facilitating the early detection of disease and other conditions.

However, FDA's overly broad interpretation and enforcement of its medical device authority limits the extent to which developers can offer these tools to clinicians and patients without going through the costly and time-consuming FDA approval process. It is critically important that FDA adopt a regulatory approach that is consistent with the legislative intent of the 21st Century Cures Act and does not prevent EHR vendors from developing the tools that health systems need to improve the practice of medicine.

Solutions and opportunities to address these challenges do exist. The U.S. health ecosystem must modernize its approach to patient health, wellness, and care by empowering patients to proactively navigate and manage their care, enabling a deeper focus on patient outcomes, and providing incentives that reward cost reduction. The industry has a responsibility to facilitate the complete, seamless, and instantaneous sharing of data with patients.

- **Longitudinal Health Record via Seamless Exchange.** Giving patients control over their healthcare begins with giving them access to their health information. Only then can we empower them to harness well care instead of relying on ad hoc management of sick care. We believe two main technological requirements are critical to making advancements in obtaining a longitudinal health record for patients, providers, and payers: 1) a national framework for health data exchange, such as the Trusted Exchange Framework and Common Agreement (TEFCA), and 2) advancing the use HL7 FHIR®-based APIs for novel and inhibited use cases.

  TEFCA provides the next generation of national exchange frameworks that address gaps in our current framework, while extending the supported exchanges purposes to include a broader range of data holders and participants. Expanding this framework to include the full record of data can help provide higher quality insights and enable rapid, centralized data ingestion from any and all provider health systems and other data holders to help create the full longitudinal health record, something Oracle Health has done successfully across hundreds of millions of patient longitudinal records.

  A deliberate migration to HL7 FHIR-based APIs as it can expand on the high priority greenfield and inhibited interoperability use cases of interest that current standards cannot address, while recognizing that supporting and selectively expanding on classic APIs and document formats remains a necessity to advance interoperability until a practical time that these can migrate as well. We therefore must maintain a holistic API perspective to continue to improve and expand nationwide exchange with all tools available.

Once a longitudinal record is available to provide a full picture of a patient's health, health IT technologies can enable advancements to enhance the healthcare experience for patients, providers, and payers.

- **Enhanced Fraud, Waste, and Abuse Protection** – Protecting citizens and taxpayers from fraud, waste, and abuse is a crucial element of controlling costs and helping make healthcare more affordable. These threats thrive in data silos where no single entity has enough context to identify, let alone prevent the loss of program funds. A centralized, real-time view of clinical and claims data, powered by a longitudinal health record that spans the ecosystem, can provide a foundation to identify and prevent common fraud, waste, and abuse patterns before funds are paid out, help immunize program budgets against emerging threats and schemes, and accelerate fund disbursement for low-risk claims to improve patient and provider satisfaction.

- **Single Point of Entry/Patient Portal.** Patients should be able to log in to an access point, a portal or app, for their whole healthcare journey. This access point should give them access to their longitudinal health record, enable them to shop for health plans, connect with their health plan, predict treatment costs, search for providers, schedule appointments, log health data between clinical encounters, view and pay bills, correspond with providers, browse available clinical trials, and seek education about medical conditions.

  Patients should be met where they are, irrespective of their native language and health literacy.

- **Digital Identities, Matching, and Linking Records** – Digital identities will be essential to establishing trust that a person can access their records across all data holders, and other users have access to that patient's partial or full record across all data holders, including their clinical, administrative, financial and consent directive data. Their digital identity must be established and then matched and linked by the data holders to the correct record.

- **Cutting Edge Digital Tools (e.g., AI, ML, and others).** Artificial Intelligence (AI) and other cutting-edge tools as they emerge should be used to enhance patient experiences, assist clinicians, streamline workflows, analyze data, and reduce administrative burden.

  Digital assistants leveraging AI can personalize the patient experience to deeply understand the needs of the patient and provide recommendations on the best method of care (i.e. in-person clinic visits vs. telehealth or community care, etc.), with clear expectations of availability and cost. With access to their digital health, patients can receive more of their

care needs at home, improving the patient experience while enabling health systems to scale their care delivery to a greater number of patients without additional staff or significant burden on clinicians.

With comprehensive, longitudinal patient data as a starting point, modern technologies and innovations can support transformation across the healthcare industry. Machine Learning (ML) and AI can assist in the identification and interpretation of data in all formats (faxed records, free text, discrete data, images). AI and ML can also assist providers, patients, and payers in identifying healthcare trends, care gaps, and patient/caregiver guidance. A unified, tightly integrated data platform with embedded intelligence can support better-informed clinical decision making and help stakeholders to deliver care more efficiently and effectively.

As an industry leader in data, analytics, cybersecurity, and enterprise solutions, we have a deep understanding of complex enterprise data needs that inform our feedback on specific questions in the attached detailed responses.

Contents

Section II.B – Patients and Caregivers

Section 1 – Patient Needs

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?*

   A modernized health care management app should drive preventative care and competition in innovative ways, going beyond health information and delivering a patient-centered experience with actionable insights and recommendations that encourage active participation in an individual's care.

   Oracle Health supports the value of a three-pronged approach, aligned with recent CMS guidance, to improve the health of populations by 1) promoting evidence-based prevention, 2) empowering patients to achieve their health goals, and 3) driving choice and competition. These elements can be accelerated by a robust, longitudinal patient record health application that provides a real time, digital front door for patient care engagement to understand, and navigate the complexities of health care.

   Within this digital front door, health care management can shift from reactive to anticipatory care by providing a cohesive, completely agnostic, longitudinal personal health record that is accessible to and guides patients throughout the care continuum. Patients can leverage embedded tools that simplify everyday health tasks such as:

   - Comprehensive and engaging views of health services across disparate systems that provide transparency for benefits coverage, eligibility, financial impact/responsibility, and opportunities for lower cost.

   - Timely nudges that highlight health recommendations and gaps in care can engage patients to actively participate and contribute to their care through patient-generated data.

   - Personalized educational content, leveraging artificial intelligence, to provide awareness of chronic condition management, mitigation and management of health concerns, tracking and trending of recent test results, vital signs, and patient reported outcomes.

- Medication management options to submit refill and renewal requests, drug interaction alerts, and support for medication adherence.

- Virtual care resources that follow the patient where they go, regardless of the venue of care (outpatient, urgent care, and bedside).

- Connections to wearables and to other applications that have patient health data.

Digital applications would ideally provide frictionless access to all clinical and non-clinical data to promote health management, with opportunities for agentic AI embedded throughout workflows to function as a personal advocate for the patient. This can help simplify the user experience and ensure patients and caregivers have continuous access to collaborative tools with care team members, leading to better management of health outcomes.

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?*

Embedded capabilities such as secure messaging, virtual care support, and AI generated resources, patients and their proxies can leverage personalized education and care navigation across providers using unified health records and intelligent care coordination. We note that for standard digital health products to be effective, they must provide meaningful engagement opportunities for patients and caregivers to manage and monitor their chronic conditions and routine healthcare requirements. In an ideal state, this means they provide a true longitudinal record of the patient's clinical and non-clinical information that deliver actionable insights used to guide the facilitation of comprehensive care plans and secure communication with care team members.

Caregivers, especially those supporting aging loved ones, face a heavy logistical burden—often while managing care from a distance. Digital health products can ease this by enabling appointment scheduling, including transportation (e.g. Uber) to and from the appointment when needed, automated notetaking to capture visit details, coordination of pharmacy deliveries, and more. Timely alerts about negative trends in chronic conditions can also help prompt check-ins with caregivers to intervene before issues arise. Truly transformative digital health products can understand the patient, caregiver, and their respective situations and adapt— e.g., suggesting mailed prescriptions when remote or local pickup is not available, or recommending appointments that align with the caregiver's schedule. These capabilities can reduce

the effort for caregivers to act as supplemental care managers while preserving the dignity and independence of those they support.

Additionally, we strongly believe in transparency in healthcare pricing and quality data, and in the security of all health data. The ideal digital health products and tools should not only assist patients and caregivers as noted above but should also enable a patient or caregiver to understand potential pricing impacts of the care when the care is being scheduled and enable a patient and caregiver to find the best quality care in their area. Allowing patients or caregivers to weigh the cost of care and understand the quality of care they can receive is essential in empowering patients/caregivers as the true consumers of healthcare.

b. *If you had a personal assistant to support your health needs, what are the top things you would ask them to help with? In your response, please consider tasks that could be supported or facilitated by software solutions in the future.*

Going beyond traditional digital health products, CMS should envision a next-generation, AI-driven health companion application designed to engage patients and caregivers across the full spectrum of physical, mental, and social well-being. This cloud-based, patient-controlled record empowers individuals to actively participate in their care through personalized insights, proactive guidance, and seamless coordination across all venues of care. Cloud based systems provide many benefits including: ease of rapid iterative innovation and evolution; scale across demands and needs; ease of multi-modal support and being less tethered to a particular forma factor; and cloud systems typically benefit from heightened security posture, especially those that exist in a FedRAMP environment.

At its core, this platform automatically retrieves data from every EHR, pharmacy, laboratory, payer, and device that supports HL7 FHIR and can share data through TEFCA nationally. This could provide a real-time, unified view of an individual's health story across a true longitudinal record for all care settings.

Key capabilities of this experience should provide personalized tools and resources so patients and caregivers can track, manage, and mitigate chronic conditions and health concerns. It should allow the patient to search for their records and ask questions. The platform should serve as their unified digital front door and surface intelligent appointment scheduling workflows that identify near term availability, proximity, and cost-sharing estimates. Automated nudges can reduce wait times, streamline administrative tasks, and minimize manual data entry errors with intuitive pre-visit

intake workflows to capture consents, demographic and clinical updates, and insurance eligibility before appointments.

Integration with wearable health devices can enable patients to provide real-time updates of their health status and receive contextualized, proactive care recommendations as an AI health assistant continuously adapts and helps guide individuals through their unique clinical care journey. Tailored education and automatically generated visit summaries based on diagnosed conditions and health concerns should also be woven throughout the digital experience. With proactive and personalized care nudges, patients can take advantage of automated tools for medication refill and renewal requests, along with recommended actions to improve care outcomes.

Automated notifications and guided actions can help patients schedule the appropriate care appointments and understand any financial impact from real-time benefit checks. Any requirements for prior authorization should also be surfaced to the patient to provide transparency of approval status and financial responsibility for each step in their care plan. Patients should be notified when prior authorizations are approved and then be able to schedule related appointments, as necessary. It is crucial to avoid surprises by highlighting the individual's financial responsibility and providing transparency into pricing requirements, estimation tools, and convenient methods for payment capture.

Certain good faith estimates are required under the No Surprises Act, however, they are not enforced in all situations at this point. Digital health tools should work to pull in any good faith estimates that are made available, as well as provision of access to any pricing transparency information published by payers and or providers to give the most comprehensive financial picture to the patient that is available.

Digital health products should also integrate with other first-class consumer services to further empower patients and improve outcomes - for example, transportation services (Uber and Lyft) and nutrition services (MyFitnessPal and Noom).

Digital health products should also connect patients with proactive interventions, including new therapies or even eligible clinical trials, to improve care outcomes and reduce costs.

Finally, keeping the patient at the heart of the experience, it is crucial they have collaborative tools and connected care team communication to better support care

management and delivery through secure messaging, on demand virtual care, and the ability to share clinical information with informed care givers.

Where traditional digital health applications may provide a static approach with limitations to effective care delivery, Oracle Health understands the tasks that are essential for engaging individuals in intelligent, patient-centric care navigation – built on a hyper-scale cloud platform that helps reduce cost and maximize security and protection of patient data.

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)?*

No, most patients do not have easy access to all their own health data, or the data of their loved ones, in a singular location. Instead, they typically have access to individual patient portals attached to each health system from which they receive care. Even when health systems participate in automated data exchange networks, it is still common for the burden of comprehensive record consolidation to fall on patients and their caregivers.

Inverting this to achieve truly patient-centered data focus requires a national exchange framework, national networks, and incentivized national entities (like CMS) to create the necessary infrastructure to provide a unified, HIT-agnostic, longitudinal data platform and patient-centered experience. A national framework eases the burden of exchange by establishing trust among participants and setting agreed upon standards for exchange. A national network optimally gives patients, and their designated caregivers simplified access, dynamic automated consent management, and visibility into new data sources and their use – without being tied to a specific HIT system.

Adopting national standards that allow patients to automatically opt in to sharing data—while maintaining transparency about data contributors—will help reduce patient burden, increase trust, and accelerate the innovative use of longitudinal health data for patient-centered care.

   a. *If so, what are some examples of benefits it has provided?*

As health information typically exists in disparate, fragmented systems, the benefits of a comprehensive patient health record (PHR) are rarely achieved, perpetuating inefficiencies in care delivery, gaps in care closure, ineffective communication, and ultimately creating a poor patient experience and sub-optimal clinical outcomes.

b. *If not, in what contexts or for what workflows would it be most valuable to use one portal or system to access all such health information?*

All patients and caregivers would benefit from a unified record experience in various ways, but patients with complex comorbidities or chronic conditions (a large portion of the CMS population) likely benefit the most from a unified system. A unified EHR-agnostic longitudinal record reduces the cognitive load necessary for patients to navigate and manage advanced care needs across broader care teams and venues - like appointment scheduling, visit preparation, and financial planning to improve patient engagement, satisfaction, and outcomes.

c. *Were there particular data types, such as x-rays or specific test results, that were unavailable? What are the obstacles to accessing your own or your loved ones' complete health information electronically and using it for managing health conditions or finding the best care (for example, limitations in functionality, user friendliness, or access to basic technology Infrastructure)?*

Obstacles to accessing complete health data largely originate from fragmented data silos and the lack of incentive to integrate those silos.

This is particularly true for less structured clinical data types like those produced by machines (Omics molecular sequences, radiology images, PFTs, ECGS, and other clinical media). With current regulatory incentives (and without pressure from federal agencies like CMS and ASTP/ONC), these results are often shared with patients as PDFs, if at all. This limits the patient's - and their caregivers - ability to understand or even find their information and hinders the opportunity for personalized insights.

ASTP/ONC should apply more pressure on actors under the information blocking framework by expansion of baseline data to support (e.g., USCDI) and regulatory incentives supporting these using standardized data formats (e.g., DICOM, HL7 FHIR US Core, and use case specific implementation guides) into a national data framework like TEFCA. This would establish an expectation of electronic exchange for these types of data which would apply pressure to actors under information blocking to enable electronic exchange in these manners to ensure they are not in violation of those regulatory requirements.

Large, national payers like CMS can incentivize use of any standards for exchange of these data types adopted by ASTP/ONC through the certification program or TEFCA.

CMS, as an agency, can also dictate requirements to healthcare providers, and certain payers, through use of regulatory action if encouragement is not enough. This would enable patients, caregivers, and others to connect their data, improving the entire experience for CMS patients and others alike.

We imagine a world in which the patient can easily view all complex data types (i.e. x-rays, clinical media, diagnostic images, etc.) directly within their digital health app. This data would present in a contextual manner with clear explanations and associated next steps, as well as the ability to share the data with any chosen recipient – a patient's family member, clinician, payer, or health system.

Additionally, advanced data concepts like clinical trials that are available to patients or other insights based on genetic sequence/variants are increasingly available but lack standards for exchange. Improving interoperability for these data concepts can help accelerate development and rollout of new, lower-cost therapies that improve care outcomes.

3. *Are you aware of health management, care navigation, or personal health record apps that would be useful to Medicare beneficiaries and their caregivers?*

There are many traditional digital health applications in the marketplace that exist with varying degrees of integration. Importantly, there are also many non-health consumer applications which are heavily used by the U.S. population.

As an industry leader in the health IT space, Oracle Health and Life Sciences has had an opportunity to work with and integrate with many digital health apps and tools, and we outline a few here. Oracle Health's platform, through our unified, EHR-agnostic approach, integrates with a variety of third-party services – like FindHelp, to address key social determinants of health (SDOH) and improve patient outcomes. This extensible framework simplifies the addition of new third-party integrations with widely adopted apps such as MyFitnessPal or Noom for nutrition management, or Uber and Lyft for transportation assistance. By connecting tools that patients already use or could benefit from, we aim to create a more familiar, supportive experience for both patients and caregivers."

In addition, we believe that enabling patients and their caregivers to connect to networks of exchange through national exchange frameworks like TEFCA, can ease patient burden and prove beneficial and useful to Medicare, and other, beneficiaries. These connections are essentially enabling patients to obtain a complete picture of their health record.

This approach not only promotes patient engagement but also opens the door to incorporating services subsidized by CMS that may otherwise be financially inaccessible to patients.

4. *What features are missing from apps you use or that you are aware of today?*

There are several features that are missing from many of the digital health products and apps today. One feature missing in many apps currently is a connection to TEFCA as a national framework for exchange. Traditionally, most patient portals are connected to a singular EHR instance using point-to-point connections. This approach is not scalable for a national level initiative when individuals receive care across multiple systems. Enabling connections to TEFCA allow digital health apps to bring patient health data more easily into a more singular record for the patient.

Transparency in pricing and quality of care are also key features that are not present in many digital health apps today. Allowing patients and their caregivers to understand the quality scoring of their providers of care, what those scores mean, and how they compare to other similar providers of care, helps to empower patients and their caregivers in determining who their providers of care should be. Similarly, allowing patients to understand what care is covered by their insurance benefits and what their potential out-of-pockets costs maybe enables patients and their caregivers to make impactful decisions for their own healthcare.

Digital health apps should seek to provide a unified end-to-end experience expanding beyond clinical data and integrating financial data, benefit coverage, social determinants, and mental health needs into a longitudinal patient record. With this whole-person integration of data, these digital health apps must evolve beyond relatively static regurgitation of aggregate information to provide truly personalized recommendations.

a. *What apps should exist but do not yet? Why do you believe they do not exist yet?*

Nearly all digital health apps enable individuals to manage fragments of their personal information, but few, if any, are incentivized or even able to unify data about the whole person. This is a result of previous incentives to select providers under HITECH/Promoting Interoperability, as well as the current framework of technology adopted and in use by most providers and patients. At the same time, it is increasingly clear that non-clinical, social determinant data (transportation, air quality, socio-economic, etc.) has a significant impact on patient engagement, access to care, and outcomes.

By virtue of being the largest insurance provider in the world (across Medicare and Medicaid lives), CMS has a unique opportunity to drive financial and regulatory incentives (and establish standards) that cultivate comprehensive data contribution and innovation in truly longitudinal person-centric application experiences that encompass the full human condition - unlocking opportunities to impact care at an unprecedented scale. CMS can provide incentives to patients that work to compile their health and social determinant data into a singular source through the use of digital health tools like PHRs.

Patient enablement of a PHR, or similar digital health product, can assist the patient in becoming more active in their care and ultimately assisting CMS in driving down the cost of care through incorporation of tools like digital assistants, recommended next steps, digital health nudges for preventive and follow-up care, and similar tools. CMS could seek to incentivize beneficiaries to use these tools through reduced co-payments or other out-of-pocket considerations, and CMS could offset costs to beneficiaries by paying for all, or a portion, of the costs for the digital health products and tools.

One important feature that is missing from today's patient-facing apps is a robust mechanism to allow a patient to report potential fraud, waste, and abuse to their insurance companies. However, having each insurance company develop their own method for a patient to report potential fraud, waste and abuse would be inefficient.

The primary reason this feature does not exist today is that no HL7 FHIR implementation guide exists for patients to report potential fraud, waste, and abuse to their insurance companies.

In 2018, the Medicare fee for service program in CMS led the way towards prior authorization interoperability by supporting the development and testing of HL7 FHIR implementation guides for prior authorization burden reduction. In 2019 the IGs were created and in 2020, the Medicare fee for service program built these prior authorization APIs into their system. CMS later issued proposed and final rules that required all CMS regulated health plans to similarly billed prior authorization APIs into their systems.

Oracle recommends that CMS' Medicare FFS program lead the way again – this time towards interoperability in patient-reported potential fraud/waste/abuse by:

- Sponsoring the development of an IG to allow a consumer to report potential waste, fraud, and abuse to their insurance companies.

- Participating in the testing of IT products that contain this feature.

- Building into the Medicare FFS improper payment prevention systems the ability to receive and act on these patient-generated alerts.

- Initiating rulemaking to require all CMS-regulated health plans to build an API to receive these patient-generated potential f/w/a alerts.

- Educating Medicare beneficiaries about this potential f/w/a reporting feature and adding to the Medicare-Connected Apps website list an indication as to which patient apps have this feature.

b. *What set of workflows do you believe CMS is uniquely positioned to offer?*

As one of the largest health insurance providers in the world, CMS is uniquely positioned to offer guidance, influence, and incentives to improve how patients and caregivers use digital health apps in their daily lives. This starts with the creation of beneficiary incentives to use digital health products and tools to create a single source of truth for each beneficiary and/or their caregivers.

CMS can enable several workflows by connecting data across each of its operations – Medicare Fee-For-Service, Medicare Advantage, and Medicaid. This collection of data could assist patients in matching records, it could assist states in aligning on technology investments and preventing duplicative technology, and it could assist in preventing waste and abuse.

CMS can seek to incentivize beneficiaries to use digital health apps and tools through reduction in co-payments or similar out-of-pocket costs and/or offsetting, or entirely covering, the cost of using these digital health apps. Reduction in out-of-pocket costs would require CMS to seek additional authority from Congress, however there is a history of similar programs like Part D's Low Income Subsidy program or beneficiary incentives to receive primary care services through ACO's enabled under CMMI authority by the Balanced Budget Act of 2018.

Within its current authority, CMS could offset the cost entirely by contracting directly with certain digital health products and apps to provide those services to

Medicare/Medicaid beneficiaries. CMS can also incent the use of price estimation and price transparency tools into PHR apps and similar digital health products.

CMS as the largest payer in the U.S. should see benefits to beneficiary use of these PHR apps and digital health products as use of these tools can assist the patient in taking control of their care, understanding their options, and receive more efficient and effective care, driving down costs to CMS as a payer.

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

CMS should begin by promoting core usability principles (like accessibility, intuitive workflows, multi-modal support, etc.), and then focusing on financial motivations that are a primary motivator for patients and caregivers. For example, CMS could work to enable digital health tools/assistants to incorporate the Medicare handbook into the process. This encourages engagement from beneficiaries, increases understanding of the program, and could decrease reliance on the Medicare call center.

To encourage uptake of digital health products by patients and caregivers, CMS and its partners should seek to incentivize patients and their caregivers. CMS could also charge select PHR apps and digital health products that interact with these portals a fee that could offset the government's costs of establishing the portal. Also, CMS could allow certain services (patient education, remote monitoring to be delivered through portal and allow for vendors to bill for the services through the portal.

By doing this, CMS can help connect patients with services or capabilities (e.g., Noom) that help further drive patient outcomes and drive down costs to the healthcare system and CMS as a payer.

The unique scale and influence of CMS on the primary and secondary health markets provides ample opportunity to encourage adoption of digital health products.

   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)?*

CMS should establish the core requirements, guardrails and requirements and allow a third party to qualify vendors for participation. CMS could also require evaluation of the digital health products to determine if it leads to higher scores on existing quality metrics to measure and convey the impact of those products. This would promote competition for achieving better patient outcomes without dictating the technical or regulatory 'how.'

As always, promoting the expansion of standard for data interoperability and emphasizing HL7 FHIR and mandatory compliance would help establish a reliable minimum dataset and access standard (e.g., USCDI) to ensure data quality, breadth, and depth meet both CMS and patient evolving needs over time. However, interoperability standards alone will not be enough if there is not sufficient incentive (positive or negative) to drive their uptake.

b. *What changes would enable timely access to high quality CMS and provider generated data on patients?*

Enabling patients to create a comprehensive, longitudinal patient record will require a secure, scalable system designed to ingest data from a variety of sources, protocols, formats, and standards. To enable advanced insights, this will extend beyond typical clinical data to operational, financial, omics, and other data.

To remove barriers to contribution CMS should incentivize or mandate participation in a centralized data sharing framework, such as TEFCA. Also, to ensure data is comprehensive, CMS must accelerate adoption of HL7 FHIR-based APIs to enable greater consistency, flexibility, and interoperability of patient health apps and the large variety of data holders they need to interact with.

CMS should work with ASTP/ONC to consider updating regulatory guidance to expand information sharing standards to ensure true interoperability and avoid vendor lock-in or "walled garden" approaches to data exchange. This can be done through adoption of standards by ASTP/ONC into the USCDI, certification, or TEFCA programs, which will lead to impacts on the interoperability and information blocking compliance sides. Additionally, CMS should be considering adoption of new Conditions of Participation (CoPs)/Conditions for Coverage (CfCs) for facilities that require a certain level of information sharing when the provider has health IT capabilities similar to the Admission, Discharge, and Transfer (ADT) requirements

adopted by CMS into hospital CoPs previously. We reiterate this idea in our response to the information blocking questions in the provider section below.

Where CMS and ASTP/ONC do not have the authority under the current regulatory framework, they should work with Congress to seek to make modifications to the current legislative framework to enable regulatory updates. For example, updates to HIPAA's privacy and security requirements incorporate considerations around PHR apps and digital health products that may not fit neatly within the current privacy and security framework.

CMS and ASTP/ONC can also seek to provide guidance to states where federal preemption of state requirements would not be effective. Participation could be tied to an incentive through the Medicaid program or required as part of approvals for state plan amendments and/or waivers. Similarly, CMS and ASTP/ONC could work with the industry and states to create a singular patient consent form to address both federal and state privacy requirements.

An effective PHR app strategy requires significant partnership and investment in scale, security, and automation to encourage real-time interoperability and intelligent insights while safeguarding patient data and meeting regulatory requirements and patient expectations for privacy and transparency.

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

By default, digital health products must be device agnostic and support multiple modes of interaction (e.g., app, text, web, phone/voice) so beneficiaries and caregivers can leverage the tools they need, when they need it, and through the method they are most comfortable with. This is particularly relevant for aging populations which are often less technically savvy and often excluded from modern digital ecosystems. Multimodal experiences empower the health ecosystem to meet patients and their caregivers where they are.

At the same time, intuitive and guided workflows are key to accessibility and ease-of-use in modern digital health products. Providing embedded digital assistants to guide user experiences in completing tasks improves engagement and experiences overall. Access to the personalized tools provided through secure guest (proxy/caregiver) experiences also extends the ability to improve overall engagement with digital health tools.

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?*

   By enabling patients to compile all of their healthcare related data on a single, PHR app or digital health product, CMS could enable the performance of analyses and identify impact of digital health products on health outcomes by the PHR apps and digital health apps. Assuming patient consent, CMS could then seek to gather this de-identified information from the PHR apps and digital health apps. If CMS was incenting the use of these apps by offsetting the cost, CMS could seek to obtain the data/reports as a requirement of payment.

   With AI-powered services and applications using the ingested data, CMS, or others, could generate insights into the correlation and causal effects of digital health products on health outcomes. For example, demonstrating how increased patient engagement can lead to more effective preventive care plans and a reduction in gaps in care.

Section 2 – Data Access and Integration

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

   Core clinical and claims data is often readily available to patients and care givers, but only occasionally in a unified experience. This includes encounters, claims, allergies, medications, immunizations, procedures, results, appointments, and notes. However, it is hard for patients to use this data as the format is prepared for providers or administrators, not patients. From this limited set, lab results, medication refills, and immunization records are typically most valuable to patients in understanding their care and next steps, even without guided assistant experiences.

   For example, Oracle Health and Life Sciences delivers highly connected longitudinal records to patients and health systems, having co-founded and/or participated in numerous local, state/provincial, and national networks and frameworks (e.g., LACIE, CommonWell, eHealth Exchange, and Carequality). The Oracle Health Information Network (OHIN) is now ramping up integration with TEFCA and in the process of applying to be a designated QHIN.

   In doing so, Oracle Health recognizes actionable, relevant insights that focus primarily on care quality and financial awareness as having high value for patients and caregivers. As a basic example, patient centered medication reconciliation and interaction checking across

health systems using disparate EHR solutions helps patients and caregivers avoid negative interactions while reducing manual burden. Additionally, displaying cost transparency alongside clinical information, quality ratings of providers empower patients to make informed decisions about their care and not delay seeking treatment, leading to better outcomes.

a. *What data is valuable, but hard for patients and caregivers, or app developers and other technical vendors, to access for appropriate and valuable use (for example, claims data, clinical data, encounter notes, operative reports, appointment schedules, prices)?*

Core clinical and claims data is valuable, but its availability is highly dependent on the documentation process and exchange standards implemented by that producing system. For example, HL7 v2 is widely used but constrained by its event-based structure and flexible formatting, often leading to inconsistent data capture. HL7 C-CDA improves structure and content but delivers static snapshots that lack support for dynamic workflows or real-time queries. HL7 FHIR introduces a modern, web-based, RESTful approach that enables more consistent, scalable, and real-time data exchange, especially when aligned with standards like US Core. However, its full potential is limited by inconsistent implementation and narrow data exposure by many EHR vendors.

Beyond this core clinical and claims set, accessing specialized and unstructured health data—like oncology staging, genetic results, or imaging—is challenging due to inconsistent exchange standards and limited requirements for providers and partners to share this data with patients. This information is crucial for personalized care, such as matching oncology or rare disease patients to clinical trials. Similarly, full claims lifecycles and complete benefit coverage details are often unavailable, making it harder for patients and providers to manage the financial aspects of care. Lastly, patient-supplied data, such as use of over-the-counter compounds, alternative treatments, or consumer app data sets, are rarely integrated into digital health experiences, limiting truly holistic guidance.

As the promise of longitudinal data expands and use cases span from individual data elements to full population-level records, a unifying standard is essential for consistent, scalable interoperability. HL7 FHIR-based APIs show promise in providing the flexibility and data consistency needed to support this range—whether through RESTful queries, push methods, messages, documents, bulk data, or subscriptions—improving data fidelity and reducing variability in interpretation.

b. *What are specific sources, other than claims and clinical data, that would be of highest value, and why?*

The healthcare ecosystem is evolving, and caregivers' understanding of patient needs is expanding to consider a holistic view of the patient, necessitating both clinical and non-clinical information. Pharmacy data, environmental factors, social determinants of health, operational data (e.g., waitlists), and more all play a large part in the efficacy and efficiency of a patient's care plan. Non-patient scoped data, including datasets from the CDC, SVI, Housing and Urban Development, census, and labor statistics provide valuable insight into ecosystem and operational factors that patients exist within, and enables higher impact personalized suggestions and recommendations. In addition, understanding their health plan, whether Medicaid, traditional Medicare, Medicare Advantage or Exchange plan. Patients need real-time access to coverage decisions and other benefit information.

All data needs to be translated into a patient-friendly format as well, so it is understandable. Using AI, patients should also be able to pose questions and receive answers.

The above is possible as today Oracle Health and Life Sciences has significant experience connecting patient activity data, pharmacy benefits managers, national open data sets, operational data, and other various sources beyond claims and clinical data. This interconnectivity has proven highly valuable for patients in proactively engaging in care, delivering caregiver education, allocating resources and supplies, launching patient engagement campaigns, and enhancing value-based care outcomes for patients.

c. *What specific opportunities and challenges exist to improve accessibility, interoperability and integration of clinical data from different sources to enable more meaningful clinical research and generation of actionable evidence?*

Technical challenges include siloed data, inconsistent documentation approaches and vocabularies, competing standards, and duplicate data, all present challenges for meaningful clinical research and the generation of actionable evidence. However, the largest barrier is that no one organization is incentivized to pursue truly longitudinal patient care – something for which CMS is uniquely positioned.

Tactically, Oracle Health recommends piggybacking off existing CURES and TEFCA

initiatives that are already impacting EHRs in 2025, but with an accelerated emphasis on HL7 FHIR and mandatory compliance to move the market away from document-based exchange to right-sized data exchange that still includes real documents (e.g., discharge summaries and referral notes), but are not limited to having to share data in a document format when the data or data set is all that is relevant. This establishes a reliable minimum dataset and access standard (supporting the scope set through USCDI) to ensure data quality, breadth, and depth meets the industry's evolving needs over time (patient portal, population health, clinical research, etc.)

Additionally, the emergence of agentic AI and LLMs represents a once-in-a-generation opportunity to unlock research and insights as the healthcare needs of the U.S. population reach new heights. Partnership between NIH, FDA, CDC, ONC, OCR, and the industry can help explore this opportunity and establish AI guidance for mitigating bias, medical device consideration, and understanding citizen sentiment.

We note that FDA should carve out and clarify AI tools from its medical device authority to accelerate industry innovation and rapidly deliver care quality improvements across the U.S. population to meet the urgency of the need. Digital health applications could provide patients with more valuable education, insights, and recommendations from medical data to improve their care, but FDA's sweeping interpretation of its medical device authority makes many of these tools burdensome to develop and maintain, particularly given the pace of innovation. At minimum, a reimbursement structure in place to offset the upfront cost of the FDA approval process, or a simplified approval process for AI tools would accelerate care quality improvements across the ecosystem.

9. *Given that the Blue Button 2.0 API only includes basic patient demographic, Medicare coverage, and claims data (Part A, B, D), what additional CMS data sources do developers view as most valuable for inclusion in the API to enable more useful digital products for patients and caretakers?*

While the data made available through Blue Button 2.0 is useful for patients and their care teams, its clinical utility is limited by both the scope of data and how it is accessed. The absence of encounter-level clinical data, which originates from providers, makes it difficult for the patient to have a full picture of their record, enabling them to identify care gaps and coordinate care across their care team. Thus, any EHI that CMS or any payer has for the patient should be accessible and shared with the patient that the EHI belongs to.

For patients receiving care in post-acute or specialized settings, the inclusion of structured data from assessments like the Minimum Data Set (MDS), Inpatient Rehabilitation Facility Patient Assessment Instrument (IRF-PAI), and Outcome and Assessment Information Set (OASIS) would offer a much more comprehensive and actionable view of a patient's functional status, cognitive health, and ongoing care needs—critical elements for managing complex conditions.

We recommend that CMS and CARIN continue the alignment of their Blue Button API to be aligned with the Patient API requirements using HL7 FHIR US Core, thus with the ONC 170.315(g)(10) requirements, enabling a consistent ability for patients to access their data consistently, no matter the source. In that context we also refer to our comments on certification requirements for HIT driving towards a more modular approach to ensure data holder expose the data they manage in accordance with those standards rather than having to develop and maintain more data that their target users do not need.

Note that we do not expect that a Patient API would still cover all relevant data as CMS or other payers simply do not have it, nor should be required to be an alternate path to facilitate access to such data as that data should and can be directly obtained from the patient's providers as they increasingly connect to national networks that are part of a national exchange framework, e.g., TEFCA.

a. *What difficulties are there in accessing or utilizing these data sources today?*

Accessing and utilizing clinical assessments like the Minimum Data Set (MDS), OASIS, and IRF-PAI remains challenging due to fragmented data ownership, limited interoperability, and the lack of centralized access. While these datasets are standardized for CMS reporting and reimbursement, they are stored in disparate systems—across skilled nursing facilities, home health agencies, and rehabilitation centers—and are typically inaccessible to patients or third-party applications. While standardized for CMS reporting, they are typically inaccessible to patients and third-party applications, and awareness of their existence is low.

Access to data through existing CMS APIs is also limited. Blue Button 2.0 only supports Medicare fee-for-service claims and lacks clinical depth. Provider-facing APIs like DPC and BCDA have seen slow adoption due to technical complexity, inconsistent data formats, onboarding friction, and trust issues related to data accuracy and timeliness. Most patient data exchange today remains provider-driven, which constrains consumer-directed models.

b. *What suggestions do you have to improve the Blue Button 2.0 API experience?*

Improving the Blue Button 2.0 API experience will require expanding its data beyond basic claims and demographics to include more comprehensive clinical information, such as encounter details, laboratory results, and post-acute assessments like MDS, OASIS, and IRF-PAI. Even the Provider API (a progression beyond DPC and BCDA) should expand beyond fee-for-service to include all claims and quality measure data. Including data from Medicare Advantage and Medicaid, where possible, would make the API more useful to a broader range of patients.

Greater consistency across CMS and provider-facing APIs, along with standardized data exchange workflows, would help streamline integration and support more seamless care transitions, e.g., full alignment with the ONC's HL7 FHIR US Core based 170.315(g)(10) requirements. Reducing friction in the login and authentication process could also make the system more accessible, particularly for older adults and caregivers. Broader adoption could be achieved through stronger partnerships with providers, EHR vendors, and trusted health applications. Taken together, these updates would make Blue Button 2.0 a more practical and powerful tool for patient engagement and digital health innovation.

c. *Is there non-CMS data that should be included in the API?*

To promote longitudinal interoperability, CMS should include data from contributing sources where possible (including clinical data from providers). Additionally, for convenience, CMS should consider inclusion of other public data sets (e.g. CDC SVIs, EPA Air Quality, etc.) appended to or integrated into contextualized API responses to promote longitudinal patient exchange beyond typical clinical and payer sources.

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

TEFCA provides a valuable opportunity to further advance nationwide data exchange building on the learnings from its predecessors and other initiatives to enhance interoperability at a national level. Key capabilities for a national exchange framework that TEFCA addresses are:

- **A common agreement** - Sign once, connect under the same terms with all other common agreement signatories removing the many point-to-point data sharing agreements, enabling faster and broader reach.

- **A trust infrastructure** – Connect with every endpoint with a recognized token/certificate/other technology that the parties are operating under the same common agreement and are trusted. Have a shared identity management and matching approach to reliably link patients to their records across all data holders.

- **Record locator services** – Ability to identify with one query all the endpoints within the U.S. where a patient has data that can be shared, subsequently subject to having authorized access within applicable jurisdictional privacy rules and patients' data sharing rules.

- **Participant directory** – A shared directory of all participants, their roles, capabilities, and endpoints/addresses for the variety of technology used to share data and/or participate in workflows.

- **Governance, standards and operating procedures** – Governance, procedures, and technical standards for a wide range of APIs utilizing the most appropriate technologies and enabling the implementation and ongoing management of the trusted exchange framework, and a neutral, final arbiter to resolve disputes.

These key capabilities facilitate the seamless exchange of EHI among more healthcare stakeholders, including patients across a wider set of exchange purposes.

Some of these elements are present in existing networks, frameworks, and collaborations. However, none integrate these at the national level in a comprehensive framework that enables participation by all across a growing set of use cases.

TEFCA Exchange initially focuses on the treatment, individual access, public health, payment, healthcare operations, and government benefits determination exchange purposes, though not all are required exchange purposes. While support for treatment has been the cornerstone for many networks and frameworks, also requiring support for individual access is a significant step forward enabling the patient to access their data and more fully participate in the coordination and delivery of their care. The other exchange purposes are initially voluntary to allow for the necessary build out of required standards and participation of the respective parties involved. It is important to ensure that individual access goes directly to the patient, and that patients are protected from bad actors that may pretend to be acting on behalf of an individual. Projects are progressing to ramp-up public health and healthcare operations, after having had little traction in other networks even though available. Other exchange purposes such as research should be enabled as soon as possible considering the opportunities to more easily access relevant data across a wider community for patients participating in such research.

The initial API focus is on IHE Document Exchange, a well-established and mature API, ensuring continuity of data sharing under a single framework while building out the HL7 FHIR-based APIs that will substantially expand on the variety of use cases that do or do not need to depend on document representations of the data, rather just the data. This expansion will have significant value to all parties enabling rightsizing data access and drive consistency across all use cases that include the same data.

TEFCA empowers patients to access and control their EHI, promotes patient-centered care and management as well as population health across all healthcare participants, and ensures that EHI is formatted consistently, reducing errors and facilitating more accurate and efficient exchange of information. TEFCA's design allows for rapid scalability and flexibility, accommodating the diverse needs of various healthcare stakeholders, and enabling the integration of emerging technologies and innovations, going beyond current national frameworks. TEFCA enables a more connected, efficient, and patient-centered healthcare ecosystem, improving the quality and delivery of care. Further focus on provider, payer, and public health-centered APIs will continue to mature and evolve the efficacy of TEFCA across the entire enterprise.

Thus, while the actual utilization is still very limited, the foundation has been laid down to provide a more robust and comprehensive national framework than has been achievable to date.

Based on current industry trends and the complexity of implementing TEFCA we estimate that it will take the provider community approximately 12-24 months to fully migrate to TEFCA. This timeframe considers the steps involved from signing up to TEFCA through go-live.

Oracle Health is committed to the success of TEFCA as also evidenced by the application of the Oracle Health Information Network (OHIN) to become a QHIN and the OHIN's current status as a candidate QHIN in the process of completing the important validation steps before it can be considered a designated QHIN.

a. *Please provide specific examples.*

   Considering that TEFCA is in its early deployment phase, it may not be clear how it currently helps advance patient access. However, the fact that individual access services are required to support, which is not the case in current national level frameworks or networks, we believe TEFCA is a major step forward and provides

benefits we must recognize. Thus, everybody joining TEFCA under the common agreement will have an obligation to respond. That alone provides a solid starting point enabling patients access to all their data across all the data holders joining and participating in TEFCA using the record locator services and directory services to more easily find and connect with all their data holders.

Additionally, as part of the Individual Access Services (IAS) exchange use case, TEFCA has a clearly established use case and process for utilizing digital identity credentialing for patients. Requirements for use of digital identity credentialing and ID tokens within TEFCA could help to prove out additional processes and use cases for digital identity credentialing outside of TEFCA as well.

b. *What changes would you suggest?*

Oracle Health has co-founded a number of large networks within the U.S. and globally, including CommonWell and supports the VA and DoD Joint HIE. From these collaborations we suggest that TEFCA specifically focuses on the following areas to further enhance its effectiveness:

- **Patient Identity Management**: Enable a patient to easily access their data without multiple sign-ons to their different data holders, including high-fidelity patient matching linking the patient's identity to their correct records. This will ensure that all other data holders, especially providers, can confidently share data with a patient's consumer app, knowing that data is shared with the right patient or caregiver. A strong focus on this topic is essential to the success of the individual access services exchange purpose.

- **Advanced Record Locator Services**: Enable having one query that provides the list of all endpoint/addresses that hold that individual's data, without having to query multiple times across multiple geographic locations. While targeted geo-fenced searches have their purpose and benefit, the base line should be the availability for the requester to get all locations through the TEFCA record locator services.

- **Full National Adoption**: Addressing the unique challenges faced by rural and underserved areas, are also essential to ensuring that TEFCA achieves full national adoption, thus being effective, and aligned with evolving healthcare needs and technological advancements, enabling providers serving those communities to be connected.

By considering these areas of particular focus, TEFCA can continue to evolve and improve, enhancing provider access to health information and promoting better healthcare outcomes for patients.

c. *What use cases could have a significant impact if implemented through TEFCA?*

A privacy and consent management framework (standards and infrastructure) enabling participants to assert confidently what data can be pushed/pulled based on jurisdictional privacy rules and patient consent to share directives that the patient can manage across all their data holders. While much data is shared, much data also remains unshared out of concern of sharing too much, thus sharing too little. TEFCA, as a national exchange framework with trust established amongst participants, can provide an environment where we can advance privacy and consent standards and the necessary infrastructure to address these issues and ideally make data exchange as a whole easier.

d. *What standards are you aware of that are currently working well to advance access and existing exchange purposes?*

TEFCA is still in its early ramp-up phase. Consequently, individual access services are not fully exercised to appreciate which standards work and which ones need advancement. Directionally, adoption of HL7 FHIR-based APIs beyond IHE Document Exchange APIs will inherently expand the ability to share data more dynamically as data elements without having to be available in documents. Documents will remain relevant for specific purposes, but not for sharing individual data elements and larger data sets. This is already noticeable outside TEFCA and is expected to evolve accordingly within TEFCA.

Alignment and advancement of patient identity management and patient matching/linking to their records will be the most critical step to take where current approach is directionally appropriate but requires more maturation and adjustments to ensure standards are used consistently within and outside of TEFCA.

e. *What standards are you aware of that are not currently in wide use, but could improve data access and integration?*

While increasingly being adopted and deployed in operational use, HL7 FHIR is still very much in its early adoption phase. Not all EHI that currently can be shared using APIs based on traditional standards such as HL7 v2, HL7 CDA C-CDA, NCPDP

SCRIPT, or X12 5010 is available using HL7 FHIR-based APIs. Thus, one should consider HL7 FHIR to not be in wide use, yet rapidly advancing with the ability to address many greenfield use cases that traditional standards cannot support given the APIs, including, but not limited to RESTful Query APIs, necessary to fully enable those use cases and do so more effectively and efficiently.

Specific examples include the use of CDA Hooks in conjunction with HL7 FHIR, subscriptions, documents. Adoption and gradual migration to expanded use of HL7 FHIR will enable increased consistency in data representations across a far greater range of use cases that have a need to share the same information, albeit in different contexts. For example, having one patient expression would substantially enhance consistent interpretation of patient demographic data.

We must recognize though that while value has been demonstrated for use by patient apps and portals, e.g., the use of HL7 FHIR in support of patient access through queries to their data, making appointments, alignment on a common standard at a national level, including TEFCA, requires a robust maturation process. TEFCA in many ways can provide an environment where such maturation can occur before these standards are enshrined in certification programs.

f. *Are there redundant standards, protocols, or channels that should be consolidated?*

We note that there are two aspects to this question to be addressed: 1) use of different standards in TEFCA vs. standards outside TEFCA for the same purpose; and 2) overlapping channels to communicate data between parties that could be simplified by focusing on TEFCA.

Redundant Standards

As we have indicated in prior feedback on the TEFCA QTF, we continue to remain concerned about the duplicative capabilities to have a rarely used messaging standard (IHE XCDR) be deployed where the DirectTrust Direct Secure Messaging Protocol can provide a consistent approach within and outside the network. We recognize its use can be limited to QHIN-to-QHIN communication, but it introduces unnecessary transformations where they are not needed.

Currently, the Public Health exchange purpose is exploring the use of case reporting submissions through TEFCA in addition to the queries from Public Health to the participants for additional data to advance their investigation and surveillance data

needs. While the latter is a prime example of addressing greenfield use cases through TEFCA, the submission process, eCase Reporting, requires a transition from one submission approach using IHE XDR or Direct that is directly to the APHL/AIMS platform under a common data sharing agreement (Carequality/eHealth Exchange facilitated) to re-routing through QHINs as described above. While arguably a small example, it demonstrates that enabling use cases that only take advantage of the common agreement and trust framework, plus where needed the record locator service, TEFCA can expand its reach to other use cases using a mix of technologies that are already widely adopted but did not have the benefit of the common agreement and trust framework to rapidly scale.

Another example would be the opportunity to align message standards where one can operate within and outside TEFCA consistently, DirectTrust Direct Secure Messaging vs. IHE XCDR to aid in the migration towards HL7 FHIR-based messaging and notification once ready.

Redundant Channels

When focusing on push transactions/messaging we note that current national networks and similarly TEFCA, as its adoption expands, and HIEs perform the same capabilities where consistently using TEFCA would reduce complexities, utilize one data sharing agreement, and enable full access across the nation.

We also want to call out requirements in some states to participate in state-based exchange, such as the California Data Exchange Framework (AB 133 in California) that create their own requirements and point to their own standards that could largely be met through a robust national trusted exchange framework like TEFCA.

We recommend that HIEs for purposes of sharing data do not impose a requirement for duplicative sharing of the same data and focus on the variety of value-add services and capabilities for the community they serve, e.g., regional/state level analytics.

g. *Are there adequate alternatives outside of TEFCA for achieving widespread patient access to their health information?*

While there are many other mechanisms outside of TEFCA that can enable data use sharing, the fact that they are outside TEFCA means they do not have a common agreement, a shared trust framework, and record locator services beyond their specific use, that can be geographic or functional in nature. Thus, it still requires such

a framework to tie them all together. To truly enable nationwide exchange, there must be a common agreement, a shared trust framework, and record locator services to enable the scalable level of data sharing that is essential. That was the vision outlined in the 21st Century Cures Act of 2016 and remains a key component of nationwide health data exchange today.

This does not mean that there cannot be other, targeted networks or Health Data Utilities (HDUs) as defined by Civitas. However, like the banking system, there is only one common framework to facilitate fundamental data sharing across all parties so that all parties can connect with everybody consistently.

11. *How are health information exchanges (HIEs) currently helping to advance patient access to health information in the real world?*

Health Information Exchanges (HIEs) have played a critical role in enabling secure, local and regional data exchange, supporting care coordination, patient engagement, public health reporting, and disaster response. They connect providers across diverse systems, improving healthcare delivery within communities and across state lines.

However, as the healthcare system advances toward nationwide interoperability, it is clear TEFCA currently represents the most viable path to scalable, standards-based health information exchange at a national level. HIEs that operate in isolation or focus solely on data sharing use cases—without broader alignment—will struggle to remain relevant. TEFCA provides a national trusted exchange framework enabling individual exchange networks to exchange amongst each other and others without the need for time consuming, individual conversations on manners of exchange and establishment of trust agreements.

To succeed in this evolving environment, HIEs must transform into Health Data Utilities (HDUs)—entities that not only exchange data but focus on providing analytics, reporting, and other value-added services that support region-level priorities and collaborative health initiatives. This model is gaining traction in states like New York, which are actively aligning their regional HIE networks with the HDU framework.

TEFCA provides the infrastructure for trusted, national-scale exchange, while HDUs extend its impact by delivering localized insights, services, and innovation. In this model, the future of HIEs lies not in serving as stand-alone data pipelines, but in becoming integrated, service-rich partners that connect communities while supporting national goals.

In short, HIEs that evolve into HDUs and integrate with TEFCA will continue to play a pivotal role—bridging national interoperability with local impact and ensuring health data serves patients, providers, and public health at every level.

a. *How valuable, available, and accurate do you find the data they share to be?*

HIE data is highly valuable for supporting patient care, public health, and research, helping fill gaps in a patient's record and aggregate longitudinal health records from multiple sources.

Receiving data through an HIE reduces the number of connections to be made, thus easier to scale, which we see being multiplied when using national HIEs. They all have the same challenges as when receiving the data from the source directly, which is primarily consistency of content in terms of quality, completeness, and adherence to standards, whether shared as part of HL7 CDA C-CDA documents, HL7 v2 messages, and emerging HL7 FHIR-based access. This makes it harder to ingest data easily in terms of de-duplication and reconciliation with minimal burden on the clinicians while achieving the most complete and relevant record for the clinician's use.

Oracle Health has observed and demonstrated the great promise that emerging AI patterns show in evolving how humans interact with data, particularly synthesizing information, and how systems can exchange data while minimizing dependence on manual transformations.

While the current state of clinical data availability is generally good and more data is being shared every day through HIEs and directly between parties, high-fidelity interoperability remains a challenge due to variations in data formats, incomplete participation, and consent restrictions that ultimately lead to data accuracy and trust issues. These data trust challenges slow uptake from health systems on more automated synchronization approaches due to risk of noise from sources outside their control.

b. *What changes would you suggest?*

To enhance the value, availability, and accuracy of HIE data, changes are needed. First, increasing data value requires expanding USCDI to include EHI and advancing HL7 FHIR as the primary standard supporting USCDI. Greenfield use cases should remain the focus, while migrating legacy APIs to HL7 FHIR-based APIs should be

reserved for cases with clear added value—such as prior authorization—where classic standards fall short or are underused.

This must be supported by data usability guidance, like that from the Sequoia Project's Data Usability initiative or the FDA's SHIELD initiative. These efforts help standardize content across formats, since data is often exchanged using multiple standards—e.g., HL7 v2 messages, HL7 C-CDA documents, and HL7 FHIR-based RESTful queries. Ensuring consistent capture and transfer of vocabulary and provenance data across health IT systems is essential to improving data quality and enabling seamless exchange of comprehensive patient information. Expanding data types to include social determinants of health—such as socioeconomic status and environmental factors—will also offer a more complete picture of patient well-being.

To boost data availability, greater participation and data sharing among providers is essential. This can be achieved through strong data governance and security policies to protect confidentiality, integrity, and access. User-friendly interfaces and APIs will also make HIE data more accessible to providers and patients.

Finally, improving data accuracy should focus on making data quality a byproduct of care delivery, not an added burden. AI-powered tools can support real-time validation, normalization, and enrichment of data as it's entered, helping ensure fidelity and usability without disrupting clinical workflows. These improvements will significantly increase the value and impact of HIE in supporting better patient outcomes.

c. *Are there particular examples of high-performing HIE models that you believe should be propagated across markets?*

We believe the future of scalable, high-performing HIE lies not in replicating specific models, but in aligning around nationwide frameworks that promote standardization and interoperability.

In the U.S., Oracle Health's work with the Joint Health Information Exchange—which connects the Department of Defense and Veterans Affairs—shows what's possible when systems integrate with national networks like eHealth Exchange and CommonWell. These integrations lay important groundwork for broader frameworks like TEFCA, which we believe offers the clearest path forward for unified, nationwide data exchange.

While regional initiatives like LACIE, TIHA, and MHC in Missouri demonstrate effective local governance and collaboration, we see their greatest value in the principles they embody—such as stakeholder alignment and data liquidity—which should inform TEFCA participation and QHIN readiness.

Internationally, efforts like OneLondon, GNCR, and Ontario eHub reinforce the importance of aligning policy, governance, and technology—principles that transcend borders and are critical to the success of any interoperable framework.

Rather than replicating specific architectures, we advocate propagating the core principles of high-performing HIE: open standards, strong governance, and national-scale interoperability working across networks—ideals best embodied by TEFCA in the U.S. context.

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.)?*

HIEs have been crucial in facilitating the secure exchange of patient data between healthcare providers, payers, and patients. However, with new entities and frameworks emerging, the role of HIEs is evolving. HIEs continue to play a vital role in the healthcare ecosystem, particularly in regional and local data exchange, public health and population health management, care coordination, and patient engagement.

HIEs are well-suited to facilitate data exchange within specific geographic regions or local communities, leveraging existing relationships and infrastructure. They can also provide valuable insights into population health trends and support public health initiatives. Additionally, HIEs can facilitate the exchange of patient data during transitions of care, ensuring that healthcare providers have access to accurate and up-to-date information. They can also provide patients with access to their medical records, enabling them to take a more active role in their care.

The evolving role of HIEs will involve adapting to new challenges and opportunities. This may include integrating with emerging technologies like artificial intelligence and machine learning to enhance capabilities and provide more valuable insights. HIEs may also need to expand into new use cases, such as supporting value-based care and population health management. Furthermore, they will need to prioritize

enhanced security and privacy measures to protect sensitive patient data and maintain trust in the healthcare system.

HIEs will also need to collaborate and partner with other entities, like private exchange networks, to facilitate seamless data exchange and improve care coordination. Private exchange networks, offered by health plans and pharmaceutical companies, can facilitate data exchange between specific stakeholders. HIEs will serve as a mechanism to connect into designated QHINs and leverage TEFCA, further expanding their role in the healthcare ecosystem.

In summary, HIEs continue to play a vital role in the healthcare ecosystem, and their evolving role will involve adapting to new challenges and opportunities. By integrating with emerging technologies, expanding into new use cases, prioritizing security and privacy, and collaborating with other entities, HIEs can continue to facilitate secure and interoperable data exchange, ultimately improving patient care and outcomes.

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?*

    a. *Examples may include the following: (1) Binding cost estimates for pre-defined periods. (2) Viewing provider schedule availability. (3) Using third-party apps for appointment management. (4) Accessing patient-facing quality metrics. (5) Finding the right provider for specific healthcare needs.*

    The most valuable operational health data use case for patients begins with improved care coordination supported by a patient's longitudinal record comprised of data from multiple sources across different EHRs, health systems, claims data, reference labs, third-party prescriptions monitoring programs, and payers. When patients compile their health data into a single, longitudinal patient health record, then there are opportunities to improve care coordination and empower patients with closed loop referrals, immediate results, fewer redundant tests, improved price transparency, and better access to care when patients need it, through on-demand telehealth and real-time access to care service availability.

    A single, longitudinal record can support safer transitions of care by providing care teams with the same information across disparate technical, geographic, and organizational barriers. Care coordination can further be supported with transparency

to the social and economic factors that impact patient care, readmission risk identification and cost transparency to support patient decision making. The true operational advantage to patients is having complete autonomy of their personal health record, with access to the entirety of their health data, as well as access to all available resources (such as in-network community programs) and control of their own care delivery (such as simple self-scheduling).

Operational health use cases for health systems and providers are improved when the health system has access to longitudinal records for their patient population. Comprehensive data sets for an entire patient population support health system in their capacity planning, resource optimization, patient throughput, supply chain management, and quality care initiatives. Predictive analytics can help health systems and clinicians use data to anticipate needs and plan to impact outcomes, reserve resources, improve financial performance, eliminate barriers, and minimize competition among providers.

b. What use cases are possible today?

Many of the most valuable operational health use cases, such as longitudinal patient care, public and social health integration, network optimization, and predictive analytics coordinated within an open ecosystem are possible today from a technological perspective but are underutilized due to lack of cohesion, data silos, and system fragmentation. There is an opportunity for national exchange frameworks like TEFCA to assist patients in compiling their health data into a single, longitudinal PHR app. However, TEFCA is in the early stages and needs time for participants to connect and for PHR apps and digital health products to begin connecting into the data sources that are available.

Based on our experience with longitudinal records, we know ongoing investments in the intersection of health data with human capital management, supply chain management, and employee resource planning show great promise in unlocking novel insights and capabilities to improve the efficiency of care, quality of care, and the patient experience while helping to optimize costs across the ecosystem.

c. What should be possible in the near future?

TEFCA is still in its initial stages and needs to be nurtured and allowed to mature. Similarly, other methods of data compilation should continue to be explored to ease the burden placed on patients and their caregivers. As patient use of PHR apps or

similar longitudinal record services becomes increasingly more popular and more widely utilized, the potential use cases of digital health will continue to expand.

Caregivers would have a complete view of their loved ones' data and information (granted by the patient) and could engage with the patient and their providers as an active member of the care team. Often, caregivers are critical in the health journey for medication access, post-discharge healing, general wellness, etc. and with the patient's approval, need to have the full account of information from both the patient and the provider in one comprehensive access point.

For a provider, this would ensure the patient is at the forefront of care, regardless of where the original encounter occurred or where their previous records may be housed. They would have the full picture of each patient and therefore could deliver the best care possible knowing all the information is present. While patients know their care the best, it is important for providers to have unimpressionable, complete data to make sound next step decisions and then in near real-time, be able to complete those next steps whether it be a referral, submitting information for prior authorization, placing orders, contacting the patients' caregivers or other care team members, and more.

d. What would be very valuable but may be very hard to achieve?

Expanding the supported set of valuable use cases where the focus should remain on cross-system integrations, not just coordination between clinical and financial systems. Layering in real-time data from human capital management, supply chain management, and employee resource planning to empower visibility into the clinical operations and the back-office intelligence can help deliver more intelligent allocation of resources to optimize care delivery and increase focus on patient outcomes.

Section 3 – Information Blocking and Digital Identity

13. *How can CMS encourage patients and caregivers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would increasing reporting of complaints advance or negatively impact data exchange?*

We do not believe that encouraging the submission of information blocking complaints, on its own, will result in advancement of data exchange. Currently, there has not been any

enforcement related to information blocking complaints, and it is unknown if there have been any investigations into any of the hundreds of complaints that have already been filed by patients, caregivers, and others. According to data from ASTP/ONC on information blocking claims (Information Blocking Claims: By the Numbers | HealthIT.gov[1]) over 700 complaints of information blocking have been filed by patients between April 2021 (when compliance requirements began) and April 2025. Nearly 200 more complaints have been filed by a third party on behalf of a patient. And yet, the industry does not have any indication as to if those are complaints with or without merit and if any investigation or enforcement actions will result from the nearly 1,000 claims already filed. Without additional information on the nature of the complaints filed and if they are valid complaints or complaints without merit, it is difficult to provide a solid answer to this question.

Discussions in which potential HIPAA violations or the potential for an information blocking complaint may lead to increased attention from a healthcare provider, healthcare organization, or Health IT developer than they may otherwise receive, however it is our experience that those actors making the threats may not have a full understanding of the compliance requirements related to information blocking and may simply be seeking additional assistance in meeting their needs. We do not believe that simply increasing the volume of complaints also equates an increase in complaints with merit or addresses the underlying issue at hand.

More education is needed amongst consumers of health care and their caregivers to understand their rights, as well as the rights of the providers, health IT developers, and others. The Interoperability Matters group under The Sequoia Project has a consumer engagement workgroup that is looking to do this type of work, among other things. There are other patient-focused groups out there doing similar work. If CMS and ASTP/ONC do not believe they have the reach to provide the necessary education, we suggest CMS and ASTP/ONC look to amplify the work already occurring which may broaden the reach of CMS and ASTP/ONC.

Just because a patient's request is not honored does not per se indicate information blocking. And increasing the number of complaints without appropriate education to the consumers/caregivers is likely to result in more meritless complaints to sort through to find those worth investigating and enforcing penalties on. An increased focus on information blocking complaints without associated understanding and education will not drive the data exchange industry forward. A real understanding is necessary as well as a sense of ownership

[1] http://www.healthit.gov/data/quickstats/information-blocking-claims-numbers

amongst patients and caregivers, and that is difficult to achieve across a population as diverse as health care consumers.

If CMS and ASTP/ONC are simply seeking additional complaints to be filed, it is likely that CMS and ASTP/ONC will be able to achieve increasing complaints at a level of consumer app developers, providers, and other health IT technology developers.

14. *Regarding digital identity credentials (for example, CLEAR, Login.gov, ID.me, other NIST 800-63-3 IAL2/AAL2 credentialing service providers (CSP)):*

    a. *What are the challenges today in getting patients/caregivers to sign up and use digital identity credentials?*

    Patients and caregivers must navigate the complexities of value awareness, privacy, and ease of use to determine how to proceed. Patients and caregivers should be able to readily understand the value of adopting a digital identity credential, the use cases it enables, the potential improvement for care quality, and particularly the implications on user privacy and data sharing. Transparency in how data is shared will be critical to building trust and driving adoption by the ecosystem.

    With many of the current solutions, patient onboarding is fragmented, requiring multiple steps, not all of which are digitally connected, to create and verify an identity, connect data feeds, and manage the identity with varying authentication methods like biometric passkeys that can require costly hardware, authenticators that require tie-in with other product ecosystems, or passwords with complex requirements that are difficult to remember. Some users may struggle to create an identity for lack of specific identification such as a driver's license or be put off by a lack of transparency for how that data is utilized. Especially for users who may not be technically savvy, this presents a significant hurdle to adoption and encourages further fragmentation as some patients embrace online systems, and others eschew them.

    Oracle Health has observed a variety of use cases and challenges resulting from digital identity in the healthcare ecosystem. Patients struggle to understand how to sign up and interconnect various identities to get a holistic view of their health data. If patients manage to connect their identities, it is often unclear how to control or manage their data to protect privacy while still receiving valuable services. Providers struggle to match record data to the appropriate patient identity, sometimes creating

multiple records for the same person across encounters or inadvertently merging records for different patients into the same virtual identity, creating further problems with care delivery and billing. Payers struggle to identify and match patient records from different provider systems into the same member record to ensure care is being delivered and paid for accurately.

The multitude of identity solutions and providers and resulting lack of common standards makes it challenging for all parties to navigate care delivery. Additionally, while use of digital identity credentials can provide some security considerations for the patient, the value to the industry is still limited. Digital identity credentialing ensures the patient is who they claim to be but still requires patient matching every time a new connection point is made, and so there is very limited burden reduction in the use of digital identity credentialing. To increase value a shared or federated patient identity needs to be associated with the credentialling process and that requires use of a trusted framework. TEFCA is a great proving ground and use case for digital identity credentialing as the patient can be given an associated ID for use in TEFCA exchange. There would still be a need for matching, but the value of digital identity credentialing increases under the TEFCA use cases.

b. *What could be the benefits to patients/caregivers if digital identity credentials were more widely used?*

Digital identity credentials, when properly implemented, can offer a high level of security with a low level of friction. In addition to a simplified patient experience, digital credentials can reduce fraud and identity theft through strong authentication while also providing patients with enhanced control over their data and access to digital applications and tools.

To ease the burden of patient matching and sharing of data, a common digital identity would be necessary, which is a separate consideration. A common digital identity can go beyond traditional patient and provider interactions and more broadly connect the ecosystem of data integrations from patient-generated health data points across other applications and services that can be harnessed to improve patient care outcomes and collaboration.

A common standard for identity in the healthcare ecosystem would enable the industry to deliver cohesive experiences for patients, providers, and payers, while fostering healthy competition. A common standard should include minimum definitions of data needed to create a valid digital identity accepted by CMS as the

nation's largest payer, such as government-issued identification, an email address, phone number, etc. CMS can act as an example for other payers. We support CMS in carrying the torch as communicated in its commitment to advance patient identity management.

Once endorsed, the standard should also be included in record locating and matching standards to ensure each identity and record has a minimum definition to facilitate data exchange. The patient consent manager services should also establish a relationship with the patient's identity to enable appropriate sharing of their consents, enabling data holders to have a comprehensive understanding of what data (e.g., encounters, conditions, test results, identifiers, etc.) that they can share or not.

The resulting standards would enable a patient to maintain full control over their health record regardless of where they go to receive care. Providers could more easily exchange data for more informed decision-making, and payers could more easily identify the appropriate records needed to ensure coverage is managed appropriately for each patient.

c. *What are the potential downsides?*

Adoption of digital identity requires ubiquity across the ecosystem to avoid the risk of further fragmentation. Delivering that ubiquity can imply a single, centralized identity system spanning all users to ensure common access, control, and management across the ecosystem, but at a higher direct cost.

Alternatively, identity standards can be defined to encourage industry adoption, but such standards often rely on one or more clear examples of successful implementation that the industry can use as a benchmark for success and may still provide for slower adoption as each solution may vary the patient experience depending on the way the standards are defined.

Standards require industry adoption across the patient, provider, payer, and technology vendor ecosystem, which can take longer than building a centralized digital identity system. Given the current state of the industry, all parties would benefit most from CMS recognizing minimum standards for digital identity interoperability to enable the industry to build on that data standard and focus investment on many of the other challenges facing the ecosystem, such as cost-effective care delivery and personalization, rather than trying to build a series of competing industry standards with varying degrees of adoption.

d. *How would encouraging the use of CSPs improve access to health information?*

While encouraging the use of CSPs may lead to improved access to health information through a standardized approach, adoption must be encouraged carefully to not unintentionally deter individuals from following protocols.

A standard approach to authentication may provide flexibility in access to digital tools, but it also could increase the burden on patients, caregivers, and proxies involved in adopting the process. CMS may benefit from encouraging voluntary adoption of CSPs to pilot streamlined efforts, or even consider a more broadly adopted, inclusive process across populations, such as a unified, digital health care ecosystem.

e. *What role should CMS/payers, providers, and app developers have in driving adoption?*

As CMS continues to expand its interoperability agenda, the focus should remain on establishing standards for data sharing and interoperability and encourage voluntary adoption of CSPs across populations. Voluntary participation efforts paired with value proposition and awareness will encourage patients to adopt the efforts and engage with the credentialing systems. CMS can offer bonus incentives to providers and health systems for patient adoption but should simply remain on the side of a voluntary and not mandated approach.

Naturally, providers become an extension of these efforts and would be incentivized to support adoption through point of care patient and caregiver conversations, educational awareness campaigns through CRM efforts, and establishing personalized automated notifications that promote enrollment initiatives.

To continue driving adoption and data access, app developers can step in and create intuitive user interfaces that bring the experience patient facing. Developers should continue to leverage additional methods of verification on top of the credentialing services, such as mobile first capabilities that utilize biometric identification and facial recognition. They should also integrate directly with core health applications and platforms, whether that is facilitated through open APIs or other toolkits.

Digital identities must be no cost for patients to drive needed ecosystem adoption. Many of the patients in need of care through CMS may lack the financial resources

necessary to shoulder the added cost of a solution designed to help them navigate the healthcare ecosystem and should not be burdened with such costs. With common identity standards in place, the industry can focus on other innovations to attract business and use those to defray the cost of meeting the standards. In addition, CMS could enforce the usage of those standards through incentives or disincentives designed to ensure all parties across the healthcare ecosystem align to those standards to ensure an even playing field.

f. *How can CMS encourage patients to get digital identity credentials?*

Patients want health care to operate in the same on-demand fashion as other digital industries, enabling on-demand access to care, information, and insights. Providing a ubiquitous, secure identity with low-friction signup and access for CMS-related health services that provides transparency for eligibility and benefit coverage, care opportunities, continuously updated care plans, and the ability to take specific actions related to care will all help drive adoption of digital identity credentials across the ecosystem.

Section II.C – Providers

Section 1 – Digital Health Apps

1. *What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved (see description in question 5 of the Patient and Caregiver section) digital health products for their patients?*

One major concern we have heard from providers involves the privacy and security of a patient's health data once it is outside the control of a Covered Entity or Business Associate under HIPAA. The privacy and security framework around PHR apps and digital health products is not as tight or well understood as those of HIPAA.

One mechanism to address this is TEFCA. Under TEFCA requirements, an IAS provider must agree to comply with essentially the same privacy and security restrictions as outlined by HIPAA. Beyond TEFCA, we would encourage CMS and ASTP/ONC to outline the current privacy and security framework along with any gaps that need to be addressed and work with Congress to address those gaps through new legislation granting authority to CMS, ASTP/ONC, or OCR to address those concerns.

Providers in rural settings would also be more likely to promote the use of digital health products if these tools helped provide greater access to care in places where access is limited. Since rural health systems are often geographically distant from patients, CMS could use incentives for rural health systems to provide additional services outside of traditional care delivery locations (e.g., telehealth and community care) all accessible through a digital health app or other channels (e.g., phone call, community health engagement, etc.) as connectivity can be challenging in rural health settings.

There should be a person-centric approach to supporting patients in rural settings that includes inherent access to both physical and virtual care, delivery of care in multiple methods, proactive home surveillance, and regularly scheduled community care services. To support patients where network access is limited, health systems require offline access for digital tools, enabling patients, and community care workers to collaborate on service delivery.

Even when patients can access traditional, in-person healthcare, health systems that operate in rural locations often lack the financial means to take advantage of innovations. The regulatory burden placed on providers, especially hospitals, is substantial, and many of the regulatory challenges require some aspect of health IT as a solution or a reduction in that burden. CMS could provide incentives to rural providers by creation of a technology add-on payment, or similar add-on payment, outlined under the CMS controlled payment system rulemakings. Additionally, CMS could consider offsetting the costs of using certain PHR apps or digital health apps by provision of offsetting costs to providers that could work with the patients to utilize these apps, or to patients or the apps directly.

Additional access limitations exist in the form of usability. Digital health applications often require the patient to download an app, have a username and password, and require a certain level of technical prowess to operate. CMS could consider separate payments to providers, caregivers, or others that assist patients in setting up and using PHR apps and/or digital health products. This would be somewhat akin to the Medicare Diabetes Prevention Program in which CMS has payments to non-provider coaches that work with patients to address weight-loss education, but this focuses on assisting patients in utilizing technology that can improve their health across several areas.

One of the best ways to empower providers to confidently promote participation in digital health apps, regardless of geographic location (or for that matter, age, or technical capability, etc.) is by ensuring patients have an intuitive user interface that facilitates all desired workflows with ease and replicates the “on demand” experience that patients expect from other digital apps for things like food delivery and online shopping. Patients deserve a

barrier-free personal health record with intelligent communication, thoughtful notifications, convenient registration and checking, financial management, and access to data from across EHRs and health systems.

a. *What are the current obstacles?*

As outlined above, the major obstacles relate to access to information and access to care, particularly in rural settings. There are technological limitations, wherein individual health systems offer their own portals, provided by their EHR vendor or third-party, resulting in patients with multiple accounts, usernames, and passwords, etc. In this way, patient access to data is disconnected and difficult to access. There are also difficulties regarding ease of use and desirability. Patients do not typically approach their healthcare data with optimism or excitement, but rather as a burden.

Additionally, with the unique CMS patient population - which consists of Medicare patients generally over the age of 65 and Medicaid patients that are generally also aged, disabled, or pregnant women and their children - there are age-related and accessibility related challenges to providing access and fostering interest in digital health apps. This means that provider organizations are only minimally capable of supporting and increasing adoption; they can provide or offer digital health applications with robust capabilities that may never truly be adopted by their patient populations.

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

Providers need to be as transparent as possible when engaging with patients and their caregivers to establish and maintain a trusted relationship. That includes communicating with patients and their caregivers through the use of digital health products and encouraging patients to use those apps when appropriate.

While providers do participate in and support the sharing of data, the patient should have full ownership and control of their health information – providing a true, comprehensive patient health record that reflects all the care a patient has received from across disparate health systems and EHRs.

Additionally, providers and payers have a mutual responsibility to surface cost and price transparency information to patients about their historical care and future care activity options – empowering patients to confidently take control of their care

without risk of financial ruin. An area of opportunity is connecting providers to key information around coverage details for patient care so the provider can have a conversation with the patient about cost of future care and the coverage resources the patient has access to.

c. *What responsibilities do providers have when recommending use of a digital product by a patient?*

Providers are an integral part of a patient's health ecosystem; however, their responsibilities lie in true patient care and documentation. Once they have appropriately treated and clinically documented patient care, the patient should have full ownership and control of their health information. CMS could institute standards and expectations that reframe what the optimal patient experience should be: a comprehensive view of a patient's longitudinal record with connections to disparate data and health system and full control of their own information that helps a patient take the lead role in managing their health. While the provider's responsibility is to address and provide appropriate documentation, it is CMS's responsibility to endorse standards and expectations about the digital product's functionality and educate patients to enable engagement.

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?*

One of the main obstacles is the current framework under which care is paid for and incentives and penalties are applied within the healthcare ecosystem. Providers are generally paid for services delivered under a Fee-For-Service (FFS) model. This model not only incents a provider to provide additional services to patients, but it also largely ignores the patient's healthcare between encounters with the provider.

Additionally, many of the VBC and APM programs look at care delivered to a patient over a limited time period and/or a limited set of circumstances. For example, most quality measures outlined under the MIPS program for ECs and TINs focus on care delivered to a patient exclusively by that provider or group. While there is logic in that, to determine the impact of care by a specific provider/TIN, it also largely ignores the impact of the healthcare ecosystem. If a patient receives a screening at one provider site there is not a need to deliver a similar screening when another provider sees that same patient; however, that provider may be dinged in their quality scoring if they do not deliver that same screening. Similarly, simple

actions like electronic prescribing should be an expectation and not something measured across each and every provider.

As the focus of healthcare shifts to looking at a patient's care across the healthcare ecosystem, including the creation of longitudinal health records for patients, payment systems, quality measure systems, and incentive/penalty programs also need to be re-evaluated to ensure they are adjusting to the changing ecosystem. Quality measures should look at patient and population outcomes across providers, when possible, based on a review of cohesive, longitudinal patient records. Payments should be considered for preventative care measures given between patient encounters. Expansion of programs like Medicare Diabetes Prevention Program (MDPP) and the Chronic Care Management (CCM) payments should be explored.

Shifts of this nature allow the provider to focus on the patient's care without worrying about addressing specific quality measurement needs. Focusing on the care of the patient should lead to increased patient outcomes without requiring providers to ensure boxes are checked at every encounter.

Some roadblocks can be reduced through comprehensive data sets connected from multiple sources (disparate EHRs, claims data, immunization registries, prescription monitoring programs, etc.) on a single platform where the data is not just aggregated but normalized and de-duplicated, but this does not fully address the burden of discrete documentation needs.

Focusing on patient and population care across encounters also allows for compilation of longitudinal records for patients, which enable newer technologies like AI/ML to assist in identification of health trends and potentially help identify potential needs of care before they become chronic. It allows for incorporation of larger data sets encompassing factors impacting health care beyond the encounter, such as certain social determinants of health. It also allows Health IT companies to focus more on innovative solutions designed to reduce provider burden and less time designing functionality to meet very specific regulatory and quality measurement needs.

Modern technology (e.g., ambient listening, AI, LLMs) is prime example of how Health IT can reduce the burden on providers to get them back to personalized narrative care documentation workflows – relying on technology to sort out discrete data needs for various reporting and insights purposes as a biproduct (not a primary focus) of the provider workflow. AI-generated summarizations and intelligent chat bots can significantly improve the speed and accuracy in which clinicians can synthesize a patient's information and make clinical decisions. When intelligence is applied against large data sets, the quality-of-care delivery can

be inherently interpreted, and metrics can be automatically qualified and met.

To this point, healthcare payment should be repositioned to support innovation within the healthcare ecosystem. This could be in the form of incentives for providers to prioritize preventative care (using the Medicare Diabetes Prevention program as a model, wherein patients and providers are incentivized to prioritize wellness and reduced risk) or shifts in how providers of care are evaluated through quality measurement and outcome determinations.

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

Patients in rural areas are often referred or transferred to higher levels of care and/or specialized providers due to varying service availability in their environment; ensuring that primary and specialist caregivers have access to the breadth of a patient's data is crucial for supporting continuity of care for these unique populations. In urban situations, patient choice may be broader, but this diversity of care options often leads to disconnected technologies across and among healthcare organizations. Though the needs or circumstances may change, interoperability of all patient data is crucial for all patients, in both rural and urban settings.

CMS and ASTP/ONC can impact some of the challenges outlined below. ASTP/ONC has regulatory authority over a large swath of the health IT space, but not all, and has regulatory authority, to an extent, over the information blocking framework. CMS has regulatory authority over most providers in the U.S. and certain payers. CMS also has influence with a large set of patients as the largest health insurance payer between Medicare and Medicaid services.

This presents opportunities between the two agencies to incentivize broadened data exchange expectations that extend beyond current regulations and minimal datasets and data types (e.g. USCDI).

a. *Current challenges in accessing different data formats.*

Access to different data formats is in many ways limited by interpretation of specifications and varying capabilities at the individual vendor level. Despite broad support for standards-based exchange formats such as IHE Document Exchange, HL7 v2, HL7 CDA, or HL7 FHIR, NCPDP, and X12, flexibility in interpretation of these

specifications can lead to incongruencies across implementations and challenges in the practical reality of data exchange. For example, differing approaches to sharing patient-and encounter-level data can lead to data duplication and overwhelm for patients, caregivers, and clinicians.

The wide variety of data formats and exchange methods also silos shared data in its receiving system; oftentimes a fax is stored in one place within the EHR or patient health record while secure messages or data exchanged via HIEs may be in separate places, if accessible at all. Some data formats are not even exchanged or shareable in a machine-readable format (e.g. scanned, faxed, or PDF documentation), making it very difficult for receiving systems to meaningfully consume, interpret, and display the data.

Additionally, certain data types provide their own limitations; file type or size can make the sharing of images and diagnostics technically challenging, laborious, and cost-ineffective. This variation in types, formats, and end-destinations within a receiving EHR often means patients and caregivers are unable to navigate the variety of exchanged data and cannot make truly informed care decisions, resulting in risks for patient safety and delays in care coordination.

b. *Impact on patient care quality.*

Today, clinicians spend far too much time looking for data and reviewing data in different formats from disparate sources, or sometimes forsaking the process of sorting through external data at all. This causes frustration among clinicians and can result in duplicate testing, delays or errors in care, and clinician burnout.

The time it can take to manually aggregate and fax data or to receive, process, and scan or import data extends gaps in care and burdens clinicians and administrative staff who should otherwise be focused on patient care and management activities. Data usability issues can also lead to dissatisfaction with patients, who are often asked to repeat their medical history multiple times to their care teams and can struggle to understand their own care histories or treatment plans.

CMS and ASTP/ONC can incent the use of data usability standards throughout the industry that increase the usability of healthcare data.

c. *Technical barriers to full data accessibility.*

Even when a connected and incentivized data network is in place, patient matching and patient identity resolution between systems can often be a challenge for patients who move, change names, become wards of the state, and other common circumstances.

Oracle Health addresses this patient linking challenge through AI-enabled patient identity resolution capabilities that handle this variability automatically to ultimately curate one unified longitudinal patient identity, even in locales (like the U.S.) where a shared government patient identifier is not available. Ideally, a universal patient identifier for the U.S. would simplify this challenge but has historically lacked legislative support.

Additionally, data usability challenges including data completeness in general and provenance data in particular, data accuracy, data normalization, and inconsistent mapping to agreed upon standards make reconciliation between systems incredibly difficult. Differing interpretation and implementations of fast-moving regulatory requirements further leads to challenges with high-fidelity interoperability; as vendors having to move to support newly required data standards and implementation guides (e.g., HL7 FHIR US Core), there is little time for provider organizations to update their connected applications and adopt the newest standards before newer standards are required.

d. *Cost or privacy implications of making all data formats interoperable.*

Making all data formats interoperable is the right thing to do, but it comes with fairly intensive resource cost (time and other resources) and there are federal, state, and tribal privacy considerations that must be considered and addressed.

Most exchange methodologies result in local copying and storage of data, often duplicate copies of the same data depending on sources and exchange methods. As national networks expand along with the breadth of data they exchange, this represents substantial duplication of cost and technical waste. Along with the costs for the storage of exchanged data, the breadth and duplication of data across disparate systems also increases costs to data producers and consumers, increases data processing time and expenses, and inflates computing and often human resource requirements to make meaning of the massive amounts of data.

There is massive opportunity for AI to automate and streamline data processing, deduplication, and semantic reasoning required with broad-scale data exchange. More centralized, secure, and highly available storage and exchange networks at a national level can also counteract this growing cost while avoiding the organizational governance and high-throughput compute limitations of fully federated or isolated models.

Additionally, as data exchange expands there will be increasing need for automated privacy risk mitigation – following standard principles that expand along with the standard exchange protocols. This includes defining standard methodology for sensitive of confidential data tagging, as well as expanding guidance for HIPAA approved deidentification methodologies (e.g. Safe Harbor and Expert Determination) where necessary.

The ability to tag sensitive data is also only one half of the challenge as the ability to share most sensitive data hinges on patient consent (and in some cases provider consent). This presents a challenge of obtaining and tracking computable consent for patients across the healthcare ecosystem. Ideally a patient would own their own consent through use of PHR apps and/or digital health tools, however some states have requirements related to centralized consent repositories and ensuring all participants have access to the best, most accurate consent for a patient becomes key in sharing data across health systems, payers, and others. Without assurance of appropriate safeguards, many in the industry may tend toward withholding more data than necessary, making compilation of a complete medical record extremely difficult.

In addition, considerations of data sharing and liability concerns (both at a regulatory and civil/criminal law level) present legitimate concerns for providers of care and healthcare organizations. Many healthcare organizations hesitate to bring all patient health data into a singular location as they believe it may reflect as ownership of that data by them and open them up to liability related to information they may not have personally seen as a clinician or liability related to actions performed or missed by other healthcare organizations. There is a need to clarify liability in these areas. CMS and ASTP/ONC may have limited ability to provide clarity in all of these situations but could work with OCR and others to address some of the considerations.

As we continue to expand the types and formats of exchangeable data, there will also be ongoing challenges to overcome related to deidentification of health data, with special focus on some non-machine-readable and unstructured concepts such as diagnostics and images.

e. *Priority level compared to other interoperability needs.*

Prioritization should be given to supporting adoption of TEFCA and USCDI availability and adherence to associated standards. TEFCA provides a national trusted exchange framework in which new use cases, data usability standards, and patient privacy and consent considerations can be piloted. Additionally, as more participants join TEFCA, enablement of these standards will become more widely available throughout the industry.

USCDI data sets continue to expand as more healthcare data is incorporated into existing HL7® standards. Use of the standards associated to USCDI can ease the burden of exchange and continue to make more data easily available for providers and others.

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?*

To support seamless patient access and integration with administrative workflows, ASTP/ONC and CMS would need to impact workflows and health IT systems (such as front-end revenue cycle products) that have generally been outside of previous certification and certain interoperability considerations. While there are administrative standards for certain transactions under HIPAA, those same administrative standards are not necessarily best suited for use by digital health products. In many cases these digital health products prefer the use of APIs.

Similar to electronic prior authorization considerations, CMS, ASTP/ONC, and others in the industry (such as the DaVinci Project) can work to outline necessary standards and implementation guidance related to administrative workflows, scheduling, and appointment making that can then be adopted by impact health IT systems. These standards would open opportunities to plug and play the best and most appropriate digital health apps and could support workflows for patient-provided intakes, as well as the ability to view, schedule, and modify appointments.

For providers, standard protocols would also enable integration and interoperability regarding provider information and cross-organization appointment scheduling. With a regulated set of standards, a centralized vendor-agnostic referral network could be created to better automate

transitions of care. Patients would have more choice, and providers would have reduced administrative burdens and resource strain, as appointments, intake forms, viewing schedules, and more could be completed ahead of the encounter, on the patient's own time.

Section 2 – Data Exchange

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:*

Oracle Health broadly supports an open and interoperable platform with a breadth of API availability, whether specifically HL7 FHIR-based APIs or other available APIs that support data liquidity within Oracle Health and broadly among the healthcare ecosystem, through customers and suppliers. As such, our responses below span both HL7 FHIR-based and classic standards-based API use cases where applicable.

Constraints for API-based exchange can be broadly applied to nearly all use cases below and are primarily centered differing implementations across vendors. While standards and specifications help interoperability and vendors can support HL7 FHIR generally, there is still limited availability of mature implementation guides for specific use cases leading to broad variability in HL7 FHIR interpretations. A few examples include encounter-focused vs. patient-focused approaches to the same API or nuances between a medication request resource vs. a medication statement resource.

Oracle Health provides health-specific API frameworks as well as its Oracle Cloud Infrastructure (OCI) services like Oracle Integration Cloud (OIC) which offer developers Platform as a Service (PaaS) capabilities with out-of-the-box support of health data standard (e.g., HL7 FHIR and HL7 v2). This allows Oracle Health and our customers to rapidly expand to meet evolving API and integration patterns.

a. *Patient Access API*

Oracle Health supports provider organizations in their efforts to enable patient access to their own health data. This access is typically available through individual HL7 FHIR-based queries, as the patient or caregiver is identifying their preferred applications and retrieving their own data. Some of our customers create and utilize their own SMART applications to access patient data, while others use 3rd party applications such as Apple Health. Additionally, patient-scoped APIs are available for

retrieval of longitudinal clinical data, claims data, and other relevant insights such as care gaps. This includes EHI Export capabilities that support patient- and population-level extraction.

Furthermore, Oracle Health is building Patient Access API functionality that can be used by interested Payer customers to allow their members to access their clinical, claims, and prior auth data maintained by payers.

b. Standardized API for Patient and Population Services

Oracle Health supports Standardized API for Patient and Population Services in several ways, including HL7 FHIR Bulk Data Export-specific and other population-level APIs used for stratification or quality measure tracking.

c. Provider Directory API

Oracle Health supports a (non-HL7 FHIR) Provider and Organizational Hierarchy set of APIs which enables curation of the Organization, Providers, Specialties, and more. These are key data elements in driving things like patient-provider attribution for key insights and other workflows where a clear understanding of existing provider and organizational relationship is needed to propose care gaps, referrals, or performance metrics to the right providers.

d. Provider Access API

Oracle Health is building Provider Access API functionality that will allow Oracle Health provider customers in requesting new patient's clinical/past claims/approved prior auth data from patient's payer.

e. Payer-to-Payer API

Oracle Health is building Payer-to-Payer API functionality, starting with HL7 FHIR Bulk Data Export option, that can be used by interested Payer customers to interact with other Payers and request newly enrolled members clinical data from their previous Payer organization.

f. Prior Authorization API

Oracle Health will act as electronic Prior Authorization (ePA) coordinator between all Oracle Health and other provider HIT and Payers – supporting Payer's Coverage Requirement Discovery (CRD), Documentation-Templates-and Rules (DTR), and Prior Authorization Support (PAS) APIs based on qualifying events taking place in an EHR or other participating HIT, e.g., registration or scheduling applications. Ultimately simplifying prior authorization and improving the efficiency of patient care.

g. *Bulk FHIR – Do you support Group ID-based access filtering for population-specific queries?*

Yes, Group ID-based filtering for a HL7 FHIR Bulk Data Export is supported.

h. *SMART on FHIR – Do you support both EHR-launched and standalone app access? What does the process for application deployment entail?*

Oracle Health supports both EHR-launched and standalone app access. The process for application deployment depends on the application author's membership in the Oracle Partner Network (OPN) (not required) and the intended user (patient, provider, business) of the application.

Patient focused applications are made available to customers by default regardless of OPN membership. For provider or business focused applications, consulting services (either provided by Oracle Health or the customer/partner) are engaged to deploy and establish application integration.

i. *CDS Hooks (for clinical decision support integrations)*

While CDS Hooks in the EHR are not yet generally available today, Oracle Health does support API calls that express risk scores, care gaps, and more that can help drive clinical decision-making.

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

TEFCA provides a valuable opportunity to take the next major step in advancing nationwide data exchange building on the learnings from its predecessors and other initiatives to enhance interoperability at a national level. Key capabilities for a national exchange framework that TEFCA addresses are:

- **A common agreement** - Sign once, connect under the same terms with all other common agreement signatories removing the many point-to-point data sharing agreements, enabling faster and broader reach.

- **A trust infrastructure** – Connect with every endpoint with a recognized token/certificate/other technology that the parties are operating under the same common agreement and are trusted. Have a shared identity management and matching approach to reliably link patients to their records across all data holders.

- **Record locator services** – Ability to identify with one query all the endpoints within the U.S. where a patient has data that can be shared, subsequently subject to having authorized access within applicable jurisdictional privacy rules and patients' data sharing rules.

- **Participant directory** – A shared directory of all participants, their roles, capabilities, and endpoints/addresses for the variety of technology used to share data and/or participate in workflows.

- **Governance, standards and operating procedures** – Governance, procedures, and technical standards for a wide range of APIs utilizing the most appropriate technologies and enabling the implementation and ongoing management of the trusted exchange framework, and a neutral, final arbiter to resolve disputes.

These key capabilities facilitate the seamless exchange of EHI among more healthcare stakeholders, including patients across a wider set of exchange purposes.

Some of these elements are present in existing networks, frameworks, and collaborations. However, none integrate these at the national level in a comprehensive framework that enables participation by all across a growing set of use cases.

Exchange purposes initially are focused on the primary use cases for treatment, individual access, public health, payment, healthcare operations, and government benefits determination. While support for treatment has been the cornerstone for many networks and frameworks, also requiring support for individual access is a significant step forward enabling the patient to access their data and more fully participate in the coordination and delivery of their care. Projects are progressing to ramp-up public health and healthcare operations, after having had little traction in other networks even though available. Other exchange purposes such as research should be enabled as soon as possible considering the opportunities to more easily access relevant data across a wider community for patients participating in such research.

The initial API focus is on IHE Document Exchange, a well-established and mature API, ensuring continuity of data sharing under a single framework while building out the HL7 FHIR-based APIs that will substantially expand on the variety of use cases that do or do not need to depend on document representations of the data, rather just the data. This expansion will have significant value to all parties enabling rightsizing data access and drive consistency across all use cases that include the same data.

TEFCA empowers patients to access and control their EHI, promotes patient-centered care and management as well as population health across all healthcare participants, and ensures that EHI is formatted consistently, reducing errors and facilitating more accurate and efficient exchange of information. TEFCA's design allows for rapid scalability and flexibility, accommodating the diverse needs of various healthcare stakeholders, and enabling the integration of emerging technologies and innovations, going beyond current national frameworks. TEFCA enables a more connected, efficient, and patient-centered healthcare ecosystem, improving the quality and delivery of care. Further focus on provider, payer, and public health-centered APIs will continue to mature and evolve the efficacy of TEFCA across the entire enterprise.

Thus, while the actual utilization is still very limited, the foundation has been laid down to provide a more robust and comprehensive national framework than has been achievable to date.

Based on current industry trends and the complexity of implementing TEFCA we estimate that it will take the provider community approximately 12-24 months to fully migrate to TEFCA. This timeframe considers the steps involved from signing up to TEFCA through go-live.

Oracle Health is committed to the success of TEFCA as also evidenced by its application to become a QHIN and is currently a candidate QHIN in the process of completing the important validation steps before it can be considered a designated QHIN.

a. *Please provide specific examples.*

   While it is still in the deployment to recognize real results, TEFCA's implementation is expected to improve provider access to health information in several ways. It promotes standardized interoperability through a larger variety of APIs and data exchange protocols, making it easier for providers to access and share patient data across different systems and networks. Additionally, TEFCA's common agreement

framework simplifies consent management, allowing patients to grant consent for data sharing more easily and enabling providers to access authorized patient data.

The overall impact of TEFCA is expected to be significant, with increased data availability and improved care coordination. By facilitating the exchange of health information between providers, payers, and patients, TEFCA increases the availability of relevant patient data, enabling providers to make more informed decisions. As more healthcare organizations and HINs adopt the framework, TEFCA's potential to advance provider access to health information is likely to grow, leading to better patient outcomes and reduced errors.

b. *What changes would you suggest?*

Oracle Health has co-founded a number of large networks within the U.S. and globally, including CommonWell and supports, the VA and DoD Joint HIE. From these collaborations we suggest that TEFCA specifically focuses on the following areas to further enhance its effectiveness:

- **Patient Identity Management**: Enable a patient to easily access their data without multiple sign-ons to their different data holders, including high-fidelity patient matching linking the patient identity to their correct records. This will ensure that providers especially, but other data holders as well, can confidently share data with a patient's consumer app, knowing that data is shared with the right patient or caregiver. A strong focus on this topic is essential to the success of the individual access services exchange purpose.

- **Advanced Record Locator Services**: Enable having one query that provides the list of all endpoint/addresses that hold that individual's data, without having to query multiple time across multiple geographic locations. While targeted geo-fenced searches have their purpose and benefit, the base line should be the availability for the requester to get all locations through the TEFCA record locator services.

- **Value-Based Care**: Facilitate the exchange of clinical and claims data to support value-based care arrangements, enabling providers to better manage patient populations and improve outcomes.

- **Care Coordination**: Enable seamless exchange of patient information across different care settings, reducing fragmentation and improving care coordination.

- **Population Health Management**: Provide access to aggregated data, enabling providers to identify trends, track outcomes, and develop targeted interventions to improve population health.

- **Eligible Participants in Treatment**: Expand the scope of covered entities, including additional types of healthcare providers such as self-pay providers, long-term care facilities, and behavioral health providers. The current Treatment purpose, which requires a response, is too restrictive as to who qualifies, disenfranchising providers who have appropriate authority under HIPAA to receive data for their patients. Considering how other characteristics can be included as currently being explored in Carequality is essential to enable broad participation. We also suggest considering bridging the connectivity with social and community services.

- **Simplify the Onboarding Process**: for healthcare providers and HINs. This would reduce barriers to participation and encourage wider adoption of TEFCA.

- **Approach API Support Holistically**: HL7 FHIR-based APIs are the future as a main pillar for TEFCA interoperability. However, we should not limit ourselves to a migration from IHE Document Exchange and IHE Messaging to HL7 FHIR-based APIs only, nor only focus on HL7 FHIR-based RESTful Queries as the main API. Other HL7 FHIR-based APIs should be in the mix (e.g., subscriptions, notifications, messages), while inclusion of classic and alternative standards-based APIs should be permitted as well considering the tremendous value that the common agreement, trust infrastructure, and record locator services can offer to many use cases at national scale. For example, eCase Reporting for Public Health under TEFCA without switching technologies would already benefit from these core capabilities. This approach can advance and accelerate TEFCA adoption, provide a streamlined migration to newer technologies where speed-to-value on older technologies is too slow, and provide opportunities for consistency within and outside of TEFCA.

  This approach is not aimed at slowing down the adoption of HL7 FHIR-based APIs plus CDS Hooks and CQL through queries, subscriptions, direct writes, and push notification/messages to support not only the relevant queries, but also reporting and complex workflows such as care coordination and management, prior authorization, referrals, privacy and consent management, quality measure and operational reporting, analytics using relevant exchange technologies.

This focus is critical advancing increased real-time access to up-to-date health information, consistency of data expressions that inherently enhance data quality by reducing/eliminating data mapping that negatively impact high-fidelity interoperability.

This shift would significantly enhance care coordination, patient safety, and population health initiatives, while also accelerating the value delivered by TEFCA across diverse care settings. Adoption and measured migration to HL7 FHIR, while maintaining a holistic API perspective will significantly strengthen the utility, responsiveness, and adoption of TEFCA-based data exchange. At the same time, it cannot lose sight of the need for relying on classic standards for continuity and targeted speed to value needs and requirements, can create a rich and robust environment to advance national level interoperability where such exchange can also benefit by running under the same common agreement and trust framework.

- **Increased Transparency and Accountability**: Establishing clear guidelines and metrics for measuring TEFCA's success, including regular reporting and evaluation of progress towards improved interoperability and patient access to health information. Addressing information blocking and incorporating emerging technologies, such as blockchain and artificial intelligence, can also enhance the security, efficiency, and effectiveness of health information exchange under TEFCA.

- **Full National Adoption**: Addressing the unique challenges faced by rural and underserved areas, are also essential to ensuring that TEFCA achieves full national adoption, thus being effective, and aligned with evolving healthcare needs and technological advancements, enabling providers serving those communities to be fully connected.

By considering these areas of particular focus, TEFCA can continue to evolve and improve, enhancing provider access to health information and promoting better healthcare outcomes for patients.

c. *What other options are available outside of TEFCA*?

Alternatives to the TEFCA exist to facilitate HIE at local, regional, and national levels. These alternatives include non-profit organizations, trade associations, and emerging technologies that enable secure and interoperable exchange of health information.

Regional or state-level HIEs facilitate the exchange of health information between healthcare providers, payers, and other stakeholders within specific geographic areas. Most are based on HL7 v2 and IHE Document Exchange based APIs, expanding into HL7 FHIR based APIs to enable secure sharing of health data. Organizations, such as the National Association of Health Data Organizations (NAHDO) and the Healthcare Information and Management Systems Society (HIMSS), provide resources and support for the development and implementation of HIEs.

At a national level DirectTrust, CommonWell Health Alliance, and eHealth Exchange are examples of non-profit organizations that provide platforms for interoperable health data exchange nationwide. DirectTrust provides a secure messaging network using the DirectTrust Direct Secure Messaging for exchanging mostly documents, but also event notifications. CommonWell and eHealth Exchange of national networks that enable secure exchange of health information between healthcare providers, payers, and other stakeholders mostly using IHE Document Exchange based APIs with HL7 CDA C-CDA document payloads, with some having started HL7 FHIR based document exchange. Additionally, Civitas provides a Patient Centered Data Home approach to connecting HIEs nationally.

Many of these networks are further connected under the Carequality framework to provide a wider, national reach for data exchange under a common agreement, common exchange standards, and a common trust framework.

These alternatives to TEFCA may offer complementary or alternative solutions for healthcare organizations, depending on their specific needs and goals. However, TEFCA provides for a next generation of national level networks that the above organization have not been able to achieve or cannot achieve.

d. *Are there redundant standards, protocols or channels or both that could be consolidated?*

We note that there are two aspects to this question to be addressed: 1) use of different standards in TEFCA vs. standards outside TEFCA for the same purpose; and 2) overlapping channels to communicate data between parties that could be simplified by focusing on TEFCA.

Redundant Standards

As we have indicated in prior feedback on the TEFCA QTF, we continue to remain concerned about the duplicative capabilities to have a rarely used messaging standard (IHE XCDR) be deployed where the DirectTrust Direct Secure Messaging Protocol can provide a consistent approach within and outside the network. We recognize its use can be limited to QHIN-to-QHIN communication, but introduces unnecessary transformations where not needed.

Currently, the Public Health exchange purpose is exploring the use of case reporting submissions through TEFCA in addition to the queries from Public Health to the participants for additional data to advance their investigation and surveillance data needs. While the latter is a prime example of addressing greenfield use cases through TEFCA, the submission process, eCase Reporting, requires a transition from one submission approach using IHE XDR or Direct that is directly to the APHL/AIMS platform under a common data sharing agreement (Carequality/eHealth Exchange facilitated) to re-routing through QHINs as described above. While arguably a small example, it demonstrates that enabling use cases that only take advantage of the common agreement and trust framework, plus where needed the record locator service, TEFCA can expand its reach to other use cases using a mix of technologies that are already widely adopted but did not have the benefit of the common agreement and trust framework to rapidly scale.

Another example would be the opportunity to align message standards where one can operate within and outside TEFCA consistently, DirectTrust Direct Secure Messaging vs. IHE XCDR to aid in the migration towards HL7 FHIR-based messaging and notification once ready.

Redundant Channels

When focusing on push transactions/messaging we note that current national networks and similarly TEFCA, as its adoption expands, and HIEs perform the same capabilities where consistently using TEFCA would reduce complexities, utilize one data sharing agreement, and enable full access across the nation.

We also want to call out requirements in some states to participate in state-based exchange, such as the California Data Exchange Framework (AB 133 in California) that create their own requirements and point to their own standards that could largely be met through a robust national trusted exchange framework like TEFCA.

We recommend that HIEs for purposes of sharing data do not impose a requirement for duplicative sharing of the same data and focus on the variety of value-add services and capabilities for the community they serve, e.g., regional/state level analytics.

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

   To support providers in making high-quality, timely, and comprehensive healthcare data available for interoperability, CMS should focus on reducing the burden of data contribution by aligning financial incentives, leveraging common provider priorities, and unlocking efficiency through use of health IT, including AI and automation.

   Providers and their health systems are more likely to contribute data when doing so aligns with existing objectives—like providing routine care, meeting quality measures, improving patient outcomes, or managing risk-based contracts. CMS can align data sharing expectations while redefining interoperability as a byproduct of routine care, not an added task.

   To achieve this, CMS should build upon the momentum of national exchange and fund centralized secure shared AI-powered infrastructure that automates data contribution, normalization, and exchange so that providers (regardless of size) can focus on their core mission of care delivery and less on managing technical infrastructure.

   In tandem, CMS should work with Congress to update reimbursement models to reflect the ongoing costs of participating in the digital ecosystem. Providers face real and rising expenses for hosting existing health IT products/services, upgrades to health IT, purchasing of new capabilities, and cybersecurity needs - none of which are currently reimbursed. Many providers, especially rural providers, operate at or below margin. Without addressing this, efforts to expand data availability will continue to strain provider operations.

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

   Providers today encounter siloed patient information, manual data entry, and duplicative workflows among other workflow complications. Complete patient records are the first step towards simplifying quality data. With the full picture, providers could reduce or eliminate

duplicative data entry. For example, if they are provided with a patient's full history across their lifetime encounters, they could eliminate the need for recording patient history and asking repetitive questions.

Most current clinical quality measures do not consider healthcare across the ecosystem and only focus on delivery of care by a singular provider, TIN, or facility. While the logic of that makes sense when looking at how a specific provider performed, it can also miss important care decisions. When a provider has access to a patient's longitudinal record, the provider can make determinations around whether specific screenings that may be monitored by a specific quality measure are necessary to perform or not.

For example, if a patient has just received a screening for diabetes or has been screened for depression by provider B and provider A knows that, then provider A would not need to screen the patient again. Provider A should not have their clinical quality measure scores related to diabetes or other screenings impacted by that decision. In this way, the current set of clinical quality measures should begin to be evaluated for ensuring performance based on all the information a provider may have access to vs only the actions taken by a specific provider, TIN, or organization. Both measurements can be used to analyze how providers perform in delivery of quality care to patients.

Additionally, aggregation of patient health data into a longitudinal health record, can enable the provider to use additional health technology such as AI which can be applied to identify gaps in care, next best actions, and quality measure initiatives based on the CMS or provider population at hand. So, providers would not only have identified areas of opportunity but could initiate the appropriate workflows based on the AI-driven insights. This could help simplify clinical quality data responsibility as they are not spending time entering data into a secondary system, not spending time analyzing the multitude of lives and data points under their care – they can be proactive in their approach to quality and instigate next steps as they are presented in near real-time.

As those initiatives are created, AI can be used to generate patient engagement and promote completion of quality measures and closing gaps in care. Patients then could use self-guided workflows within a national citizen portal, supplied by the comprehensive longitudinal record, to complete the next steps whether that be scheduling an appointment, communicating with their provider, or updating their patient diary with new information. To close quality measure gaps, providers need patients to actively participate in their care – with proactive engagement and intuitive workflows, patients can easily respond to those prompts and would be more willing to take the next steps.

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

Bulk FHIR exports from EHRs to CMS could help simplify clinical data quality submissions as it would reduce the provider and health system administrative burden for submission and enable regularly scheduled data pulls for performance reviews. To facilitate the use of bulk exports, CMS could stand up a cloud-based quality measurement service that ingests standards-based data (HL7 FHIR R4, Bulk FHIR, C-CDA, claims, etc.) that could return measure scores and provide patient level detail from a comprehensive longitudinal record that would remove duplicative logic that currently exists in EHRs and registries today.

Providers should focus on capturing clinically relevant data and CMS should supplement these efforts by performing the necessary calculations. Additionally, harmonizing data models and submission windows and aligning eCQM, MIPS, APM, and other quality measure requirements would simplify and reduce the number of exports needed so the same presentation of data could satisfy several different requirements at once.

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

Interoperability and quality reporting have a significant amount of overlap regarding data needed, types of data, and data ingestion needs. Therefore, the same data could be used for multiple different use cases.

For example, Oracle Health provides a longitudinal health record product to our clients. Once data is ingested, it is normalized and standardized to our common data model in order to consolidate the data into industry standard terminologies. Because the data is organized into a standard format, as stated, the same data can be used for multiple different use cases including interoperability and quality reporting use cases.

The data could then be connected and ingested into the platform for those use cases with very little front-user uplift from providers. They would have the faculties to export and distribute their data as it is processed in near real-time to the appropriate regulatory bodies as quality reporting responsibilities arise. Overall, the platform

consolidates data and supports different source data that can roll-up into comprehensive quality reporting.

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?*

We believe there are several requirements CMS should consider for data registries to support.

- **Standards-Based Exchange**
  Registries should both ingest and expose quality data via the full ASTP/ONC certification compliant HL7 FHIR-based stack—HL7 FHIR Bulk Data Export for large, periodic extracts and appropriate HL7 FHIR-based RESTful APIs for smaller, event-driven updates, reporting, and other use cases, while using HL7 QI Core and DEQM implementation guides for communication of quality measures, whether inbound or outbound.

- **Fast, Actionable Feedback**
  Patient-level gap lists and refreshed measure scores returned within 24 hours of data receipt—turns the registry from a retrospective scorekeeper into a near-real-time clinical decision support tool. Results should flow back through the HL7 FHIR API endpoints, so care-team dashboards and EHR side-panels update automatically while the patient is still under active management.

- **Transparent, Auditable Logic**
  Registries must publish every digital measure as a versioned HL7 FHIR Measure resource with accompanying CQL and test patients. An open "explain-my-score" API should allow providers to query any patient or population result, see numerator/denominator placement, and download the evidence bundle—streamlining dispute resolution and fostering trust in the calculations. Also, providing visibility in real-time to measure logic changes resulting in scoring truncation and year over year logic modifications. Maintaining a stable measure base, which is not drastically changing from year to year with measure additions and removals, enables consistent reporting for providers.

- **Uniform Security and Identity**
  Leveraging TEFCA's trust fabric, registries should require SMART Backend-Services authentication, a single credential set—reusable across all qualified registries.

As a leading payer in the healthcare space, CMS should consider implementing or endorsing industry standard language for quality measures like CQL and broadening USCDI wherever possible. As healthcare grows and the population needs shift health systems, providers, and patients themselves will increasingly need more data.

Section 3 – Digital Identity

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

From a provider perspective, there would be minimal direct incentive for the adoption of patient-centered digital identity credentials as most patient access today is enabled through patient portals and APIs that are provided by their EHR or third-party developer. Unless it becomes mandated, providers already have a patient matching methodology in their proprietary credentialling systems, and the direct benefit would truly impact the patient.

On the contrary, unlike a traditional EHR linked identity, a federated, independent digital identity can incorporate much more health data more easily than a proprietary identity system, which enables data beyond the provider and patient relationship directly. This can in turn, equip providers with more patient information to utilize in the longitudinal record of care and drive better care outcomes.

Should CMS encourage providers to accept digital identity credentials, upfront funding to offset the material cost would be an initial starting point. Shifting that financial burden off the provider or the patient would be the first step in promoting adoption. Additionally, if there was any value that could be highlighted to demonstrate the reduction in manual administrative burdens, for example, if support issues transitioned to the credentialling service provider and off the provider, there could be potential benefit in highlighting the ROI from that shift.

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

Should CMS choose to encourage implementation of unified digital identity credentials, acceleration of the transition would be dependent on key factors including:

- Unified TEFCA patient matching identifiers to provide accurate and reliable patient matching (lacking a true universal patient identifier).
- Technical support for organizations to transition software, in addition to a seamless migration of existing patient and user credentials to the new system.
- Automated provider attribution within the new identity system to ensure a frictionless transition.
- End user support for ongoing adoption, how-to guides, and tutorials for troubleshooting and issue resolution that are in convenient locations for providers and patients to access.

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?*

Digital identity systems can promote a digital healthcare experience that is highly secure and convenient by reducing the number required logins, streamlining access, and validating patient identification. Promoting the value that these digital health tools provide can help create further awareness and usage of patient privacy and access capabilities and highlight additional needs to allay many of the common concerns regarding data access and privacy.

Patients, caregivers, and providers need to see that these digital health products are effective in not just enabling convenient and secure access, but also by supporting caregivers, improving adherence to care recommendations, streamlining provider workflows, reducing costs in care, and improving patient outcomes. The patient privacy and access balance depends on the value that a new identity system is going to bring that it didn't previously to justify the additional data sharing needs, risk and authentication steps required.

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

    a. *What are the challenges and benefits for providers?*

    The most significant challenges for providers will continue to be the time, resources, and cost investment for adopting a federated identity system. These resources are limited and finite, so the biggest hurdle to address will be providing the support from a technical perspective and financial perspective.

    On the contrary, the true benefit lies in the extension of data sharing that a federated identity could supply across systems. This opens opportunities to leverage additional patient data which can be further used in delivering more efficient care, which leads to reduced costs in care and improved outcomes overall.

    b. *How would requiring their use improve access to health information?*

    If a federated identity was required, it could ultimately provide a secure linkage of patient data across disparate systems, including patient facing platforms, provider platforms and care settings. This would create a unified data ecosystem between patients and providers by providing an opportunity to link patient generated data including remote monitoring devices, patient portals, smart devices, and the like. As that data extension becomes captured in the longitudinal record, it can be leveraged in predictive analytics, population health management, and risk stratification to better produce wholistic patient care.

    c. *What are the potential downsides?*

    While digital credentialling could benefit or streamline provider workflows, there are potential hurdles or downsides that could occur. Initially, there is not clarity where the material cost (assume about $2 per user, per year) would fall. Would implementation increase the financial burden on the organization, or be passed along to the application developer? Additionally, without offsets to cost and implementation support, providers may not see value in adopting a credentialing system as proposed.

    d. *What impact would mandatory credentials have on a nationwide provider directory?*

A mandated credentialling system amongst providers could promote a more accurate, automated, and up to date repository of provider networks that could be tied across EHRs, payers, HIEs and digital health apps and promote enhanced connectivity than what currently exists in static directories today. Consideration should be given to a duplication of provider directories; however, to ensure that there remains a single source of truth that reflects provider adoption.

e. *How could digital identity implementation improve provider data flow?*

With a more streamlined approach to provider credentialling, a true interoperable experience can be facilitated through more real-time provider communication and data exchange of patient information. This bi-directional exchange also shifts focus to more collaborative care for patient needs.

f. *Would combining FHIR addresses and identity improve data flow?*

If the intent of the question is what the importance is of using one's identity to identify where an individual's data is accessible using FHIR addresses, we would indicate that it is critically important. When an individual's identity is properly matched to a data holder's records for that individual and record locator services such as those envisioned in TEFCA at a national scale are deployed, then the individual, and anybody else needing to access that individual's records within their authorizations would have a more accurate and complete set of endpoints/addresses to access the data. These endpoints/addresses may be representative of HL7 FHIR-based APIs or IHE Document Exchange APIs or other APIs that may be associated with these record locator services.

11. *How could members of trust communities (for example, QHINs, participants and subparticipants in TEFCA, which requires Identity Assurance Level 2 (IAL2) via Credential Service Providers (CSPs)) better support the goals of reduced provider and patient burden while also enhancing identity management and security?*

To reduce provider and patient burden while enhancing identity management and security, trust community members can implement various strategies. One key approach is to streamline identity assurance processes through automated identity proofing and verification, meeting Identity Assurance Level 2 (IAL2) requirements. This can be achieved with the help of Credential Service Providers (CSPs). Additionally, Single Sign-On (SSO) solutions can be implemented to enable providers and patients to access multiple applications with a single set of credentials.

Federated identity management systems can also be established to enable secure sharing of identity information between trusted entities, reducing redundant identity proofing and verification. Patient-centric identity management approaches prioritize patient convenience, security, and control over personal identity information. Furthermore, standardized APIs and interoperability protocols can facilitate seamless communication and data exchange between systems, reducing burden on providers and patients. Education and awareness programs can also be provided to inform providers and patients about the importance of identity management and security.

Continuous monitoring and evaluation of identity management and security measures are crucial to identify areas for improvement. Collaboration and information sharing between trust community members, CSPs, and stakeholders can help stay informed about emerging threats and best practices. User-friendly and accessible identity management solutions can accommodate diverse user needs, including those with disabilities. Regular security audits and risk assessments can also be conducted to identify vulnerabilities and ensure alignment with industry best practices and regulatory requirements.

By implementing these strategies, trust community members can better support reduced provider and patient burden while enhancing identity management and security. This ultimately improves the overall healthcare experience. With streamlined identity assurance, SSO solutions, and federated identity management, providers and patients can enjoy a more convenient and secure experience. By prioritizing patient-centric identity management and implementing standardized APIs, trust community members can create a more efficient and effective healthcare system.

Section 4 – Information Blocking

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 there are several exceptions and/or conditions of exceptions that ASTP/ONC should consider revising. These include the timeline conditions of the infeasibility and licensing exceptions and the manner exception. Additionally, there was an exception proposed in the HTI-2 NPRM that we do not believe should be finalized – the requestor preferences exception.

a. Infeasibility Exception

The infeasibility exception, including the responding to requests condition, has existed since the initial adoption of the information blocking regulatory framework under the 21st Century Cures Act final rule in May of 2020. Since the initial rulemaking, ASTP/ONC has modified the conditions under which the infeasibility exception can be claimed, but has not modified the responding to requests condition, which contains a 10-business day requirement (we understand ASTP/ONC did propose some modifications in the HTI-2 NPRM that have not been finalized).

We strongly believe the 10-business day requirement of the responding to requests condition needs modification. First, we encourage ASTP/ONC to finalize the modifications proposed in the HTI-2 NPRM. Second, we encourage ASTP/ONC to modify the responding to requests condition, especially when it comes to the segmentation condition.

Our concern on the responding to requests condition working with the segmentation condition relates to how specific scenarios routinely play out for patient and/or caregiver electronic access to EHI. If a healthcare provider seeks to withhold specific data under the prevention of harm exception, the privacy exception, the protecting care access exception, or simply to meet a state, federal, or tribal law and cannot unambiguously segment out the necessary data, that would normally lead to the provider, or other actor, being able to claim the segmentation condition of the infeasibility exception. However, to claim the segmentation condition, the provider, or other actor, must also meet the requirement to provide a written response within 10-business days of the request.

The issue that routinely plays out is when a patient/caregiver seeks to access information through their patient portal or through a third-party application using the APIs enabled by the provider and the healthcare provider has restricted access to an amount of data allowable under the segmentation condition but is left to wonder how to routinely meet the requirement to provide a written response to the patient/caregiver outlining the limitation. While there are many creative ways to achieve this, we encourage ASTP/ONC to modify the responding to requests condition to provide clarity on this scenario and enable providers to meet the condition by providing a written response once, within the portal or in writing before the patient/caregiver accesses the information, or to enable the provider to meet the requirement by providing clear next-steps for the patient/caregiver to access the additional EHI or appeal the restriction.

b. Licensing Exception

We encourage ASTP/ONC to provide more flexibility to actors in meeting the timelines of the licensing exception as well. Currently the licensing exception requires actors to begin negotiations within 10-business days of the request and to complete negotiations within 30-business days. While we always strive to work as quickly as we can when it comes to contracting new deals, the timeline under which licensing deals are negotiated is not under the complete control of Oracle Health or other Health IT developers, or actors in general. ASTP/ONC should consider a timeframe to begin negotiations, but not require a timeframe to complete negotiations. If ASTP/ONC is concerned that a Health IT developer or other actor may stall out negotiations, then it should consider a timing component on how long the actor has to respond after the other party responds. But a timeframe to complete negotiations enables the requesting party to stall negotiations simply to ensure the actor cannot claim the exception. And while we understand that just because an actor cannot claim an exception does not mean they have violated the information blocking compliance framework, it makes it much easier to create and operate a compliance program when the timelines for the exceptions are realistic and within the control of the actor.

c. Manner Exception

The third current exception we encourage ASTP/ONC to modify is the manner exception. The manner exception has been modified by the HTI-1 final rule to remove the content portion of the manner exception. The manner exception has also been the focus of at least one court case in which the court considered if a violation of the information blocking definition occurred and if the defendant was entitled to claim any of the exceptions. A key consideration of that court decision, as well as the 4th Circuit's decision, was the amount of negotiation required between the actor and the requestor before an actor is allowed to consider claim it 'cannot reach agreeable terms' with the requestor. We encourage ASTP/ONC to clarify, within the exception itself, that negotiation between the two parties is required and the actor cannot simply indicate that terms were offered and rejected. We believe this will help ensure clarity in the industry and alignment of court cases, and OIG decisions, in the future.

d. Requestor Preferences Exception

Finally, we encourage ASTP/ONC not to finalize the requestor preferences exception that was proposed in the HTI-2 NPRM. We believe that this exception is unnecessary, provides little to no value, and creates additional burden to implement. The ability to honor a requestor's preferences should already be built into the definition of information blocking or covered under the existing Manner Exception. By the very nature of a request for access, exchange, or

use of EHI, honoring the request cannot be an interference, material discouragement, or prevention of access, exchange, or use of EHI.

This type of consideration of a request was seemingly covered in the recently removed content portion of the former Content and Manner exception, now the Manner exception. If ASTP/ONC believes there is a need for express language in an exception to meet this consideration, it should simply bring back the content portion of the Content and Manner exception and do so in a way that clearly indicates a request for a set of EHI can create a scope of EHI to be provided to the requestor. Otherwise there seems to be simply no value at all for this, only burden and confusion.

The proposed creation of a separate exception will impose additional documentation requirements without adding any meaningful value. The proposed exception itself requires the requestor to outline their request in writing, which will need to be maintained, and requires the actor to respond to that request. The exception allows that response to be verbal, however considering the actor will need evidence of this discussion for any potential information blocking investigations conducted by OIG for which the actor may seek to use the exception, the actor will need to maintain a written record. More than likely these conversations are already occurring and being documented in case of a potential complaint or investigation (and now a potential lawsuit with information blocking being taken up as a private right of action).

The exception provides no value because the actions taken into consideration for this exception should already be taking place in order to honor a request under current structure. The exception creates additional burden and confusion because it creates a new pathway for actors to claim an exception that can already fit into existing structure and will likely lead to additional documentation and process that is unnecessarily duplicative. Potential exceptions like this, that are unnecessary and seem to be simply for the sake of creating new exceptions without providing value, will lead to information blocking compliance becoming even more burdensome and will increase compliance efforts and costs.

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

The definition of health care providers under the scope of the information blocking requirements is very broad, but only a select few within that definition have had any disincentives outlined by 'appropriate agencies.' Through previous rulemaking from the Department of Health and Human Services (HHS), along with ASTP and the CMS, it was

clear the thought at the time of rulemaking was the agencies were limited to creating disincentives via only a narrow list of pre-existing CMS programs under which the exchange of EHI is a key factor.

This presents an immediate issue that has led to only a select few provider types being subject to disincentives, and the impact is that a significant portion of stakeholders who directly affect the exchange of health data are not further incented to accelerate their standards-based exchange practices. More specifically, only those few healthcare provider types who have already had incentives to adopt, implement, and/or use certified health IT, or any health IT (such as through participation in CMS programs that measure interoperability), are affected by the recently finalized information blocking disincentive structure.

Included in the groups therefore not currently being motivated by information blocking disincentives are several other critical stakeholder groups, such as labs, imaging centers, and pharmacies. These groups have proven themselves less likely to adopt standards-based exchange practices, still sticking in many cases to proprietary approaches to interfaces, for example, and adding unnecessary costs to the healthcare system. HHS needs additional authority – not just within CMS or ASTP/ONC – to consider a broader opportunity for disincentives.

Further, it must be noted that the current health IT model leaves out many healthcare providers from participating in the same robust exchange environment as other provider types, particularly those in behavioral health, long-term care, and post-acute care settings. They have historically not been incentivized to adopt interoperable health IT systems, and they often face significant financial and technical challenges in upgrading their IT infrastructure. This puts them at a disadvantage when it comes to meeting the interoperability requirements of the 21st Century Cures Act, as well as elevating their information exchange capabilities.

We strongly encourage the consideration of targeted incentive programs for these provider types to accelerate progress in interoperability across all areas of care. CMS may seek to incorporate the exchange of EHI through quality measure programs for some of these provider types and stakeholder groups. Quality measure requirements can be incorporated into existing programs without any new authority being issued to CMS. Similarly, the adoption of requirements into the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), or similar requirements or seek a new manner of incorporation of the exchange requirements.

We encourage CMS and ASTP/ONC to work with Congress as well in consideration to provide additional authority to CMS, or other appropriate agencies, to develop programs focused on the adoption, implementation, and use of health IT, certified or not.

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

We offer a few suggestions related to providers submitting information blocking complaints. Based on published information blocking claims data from ASTP/ONC's website, just over 75% of all information blocking claims have been filed against healthcare providers. In addition, about 68% of all claims have been filed by patients or third parties on behalf of patients. While we cannot draw any specific conclusions without additional detail from the published data, this does indicate that providers tend to be the ones caught in the crosshairs because they are the ones most directly interacting with the patients and caregivers.

Based on this data, we can assume that as these claims against healthcare providers are investigated, the investigation may shift from the provide to the health IT developer or HIE/HIN in certain cases when the healthcare provider has evidence that the blocking was not a result of any of their actions. So, by simply investigating the claims, there may be an increase in the number of claims that need to be investigated against actors other than the healthcare provider.

Additionally, as enforcement actions by OIG, or the courts, begin to reveal with more clarify what is and what is not information blocking, it is likely that providers, and others, will begin submitting additional claims. It our believe that there are many providers, and third parties, that are afraid to file a complaint because it may impact their business relationship with a specific Health IT developer or other actor. As clarity is obtained around what is considered to be information blocking, it is likely that more claims will be filed by healthcare providers and others because the fear of repercussions will be reduced by the reality of the consequences of the actions being performed by the actor. To this point, additional education to providers outlining if, and when, their identity would be revealed to the actor being investigated may lead to additional providers filing complaints.

Another consideration is for ASTP/ONC to begin performing their own investigations of Health IT developers with enforcement through the certification program. Currently, there has been no known investigation and enforcement action by OIG on any of the over 1300 information blocking complaints filed. Some may assume there will not be any action and therefore there is no need to file a complaint. If there was activity related to investigation and

enforcement of the information blocking claims submitted, even if it was only on ASTP/ONC's end and focused on Health IT developers' compliance with the conditions and maintenance of certification, that may be enough to spur others in the industry to begin filing claims of information blocking. As an example, the recent court cases in which information blocking has been raise has increased the amount of discussion around compliance with the information blocking requirements significantly with none of the cases being fully finalized.

Similar to our comments above in the patients and caregivers' section, we also want to reiterate that just because there is an increase in the number of claims being filed does not mean there is also an increase in the number of claims with merit being filed.

Section II.D – Payers

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*?

   We note that TEFCA has the essential elements (common agreement, trust infrastructure and primary standards (IHE Document Exchange with HL7 FHIR-based API support on the immediate horizon) to advance health care operations use cases between payers and providers. Initial pilots and explorations are in flight in collaboration with HL7 Da Vinci project in particular through 10x10 and Trebuchet projects to identify how to realize a number of use cases.

   The primary challenge is around the question whether the healthcare operations exchange purpose and its use cases should be "free." While there is more clarity around treatment-based data sharing being free given the reciprocal nature and symmetrical characteristics of the data sharing use cases, such reciprocity and symmetry is not clearly understood between providers and payers. Having the opportunity to charge where there is limited symmetry in the data exchange in terms of data volume and/or value enables the community to understand and allocate cost with the appropriate parties as overall balance of equitable contribution to the necessary infrastructures and processes is clear.

2. *How can CMS encourage payers to accelerate the implementation and utilization of APIs for patients, providers, and other payers, similar to the Blue Button 2.0 and Data at the Point of Care APIs released by CMS?*

To accelerate the adoption and effective use of APIs, similar to Blue Button 2.0 and Data at the Point of Care (DPC), CMS should pursue a coordinated strategy that combines regulatory action, incentives, and technical support.

Expanding current regulatory related interoperability requirements, CMS can mandate certain payers to implement standardized APIs that support not only claims data exchange but also access to key non-claims data elements. These include enrollment status, member assignment for attribution, risk stratification outputs, care gap information, ACO performance metrics, and other derived data essential for managing patient care and population health.

Strategic use of incentives, such as integrating API functionality into Medicare Advantage Star Ratings, tying adoption to value-based care (VBC) performance metrics, and reducing administrative burdens, can encourage payers to prioritize development and deployment. Support for certified API solutions and industry-standard implementation guides will help ensure consistency while lowering barriers for smaller or less-resourced payers.

The overarching goal is to ensure APIs deliver timely access to longitudinal patient data, including both raw and derived elements, in ways that are meaningful across both Fee-for-Service and VBC models. Done well, this positions payer APIs as critical to achieve a more connected, transparent, standardized, and patient-centered health ecosystem.

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?*

CMS can play a crucial role in promoting the adoption of digital identity verification in the healthcare industry by establishing standards for digital identity verification. CMS can ensure that payers understand the requirements and benefits of accepting digital identity credentials (e.g., those certified to NIST 800-63 rev.3 such as CLEAR, ID.me, Login.gov, or others), such as the timely and efficient, electronic authentication of patients and their partners.

It is important to note that two of the referenced credential service providers are pay-for-use and require establishing business agreements to utilize the service. CMS could consider creating or encouraging the creation of a larger federation network where costs are shifted to the consumer or other parties, eliminating some of the business barriers. Having a federation network would reduce operational barriers of having to maintain registration with each credential service provider.

CMS can also incentivize payers to accept digital identity credentials by offering funding, financial rewards, or bonuses for those that adopt and implement digital identity verification.

Additionally, CMS can develop a framework for digital identity verification, outlining the requirements and best practices for payers to follow when accepting digital identity credentials. Collaborating with industry stakeholders, such as payers, providers, and digital identity credential providers, can also help promote the adoption of digital identity verification and develop standards and best practices.

To support the implementation of digital identity verification, CMS can provide technical assistance to payers, develop a digital identity verification toolkit, and establish a digital identity verification pilot program. This will allow payers to test and evaluate digital identity verification in a controlled environment. Furthermore, CMS can monitor and evaluate the use of digital identity verification, identifying areas for improvement and providing feedback to payers and digital identity credential providers.

By implementing these strategies, CMS can encourage payers to accept digital identity credentials from patients and their partners, promoting the adoption of digital identity verification and improving the security, convenience, and efficiency of healthcare services. This can lead to better healthcare outcomes and a more patient-centered approach to care. By providing funding for digital identity verification and developing a digital identity verification roadmap, CMS can ensure a successful and widespread adoption of digital identity verification in the healthcare industry.

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 that incorporates HL7 FHIR endpoints and digital identity credentials would offer significant benefits to payers. This directory would enable payers to access accurate and up-to-date provider information, facilitating seamless data exchange and reducing errors. The use of digital identity credentials would also provide an additional layer of security and authentication, ensuring that only authorized providers can access sensitive patient data.

The directory would streamline provider onboarding, automating the process and reducing the administrative burden and costs associated with manual data entry and verification. It would also simplify HL7 FHIR endpoint discovery, enabling payers to easily connect with providers' HL7 FHIR servers and exchange clinical and administrative data. This would improve interoperability with providers, reducing the need for manual data entry or faxing and facilitating care coordination.

By using a standardized directory with HL7 FHIR endpoints, payers could improve care coordination by identifying and connecting with providers who are part of a patient's care team. This would lead to better-informed decision-making, improved communication, collaboration, and better patient outcomes. The directory would also enable payers to engage with providers more effectively, facilitating communication and collaboration, and improving the overall provider experience.

The implementation of a nationwide provider directory with HL7 FHIR endpoints and digital identity credentials would also help payers comply with regulatory requirements, such as the CMS Interoperability and Patient Access final rule. Additionally, it would provide payers with improved data analytics capabilities, enabling them to better understand provider networks, identify trends, and make data-driven decisions. This would lead to increased efficiency, as payers could automate many administrative tasks and focus on higher-value activities.

Overall, a nationwide provider directory with HL7 FHIR endpoints and digital identity credentials would provide payers with a robust and secure platform for managing provider data, facilitating interoperability, and improving care coordination. This would ultimately lead to better patient outcomes, reduced costs, and improved provider engagement, making it a valuable investment for payers.

We do note that a robust national healthcare directory is not limited to capturing HL7 FHIR endpoints, but endpoints and addresses that are used for recognized standards-based APIs such as IHE Document Exchange APIs and DirectTrust Direct Secure Messaging APIs.

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

Payers can cut much of the administrative friction that keeps clinicians from patient care by pairing a common set of standards with practical, real-time support. At a high level, the formula is simple: transparently standardize what must be reported, automate how it is gathered, and feed timely insights back to the point of care. Concretely, that means:

- **Adopt one harmonized measure set and data format.** Incentivize payers to align their quality programs to the same USCDI+/HL7 FHIR or QDM specifications used by CMS, so a single extract meets every requirement, eliminating dueling spreadsheets and proprietary portals.

- **Shift calculations and reconciliation upstream.** For agreed to use cases feed minimum necessary clinical and claims feeds into a payer-hosted engine, run the numerator and denominator calculations centrally, and return patient-level gap lists plus clear audit detail.

- **Leverage data you already hold.** Enrich clinical feeds with claims, pharmacy, and lab results, then supply monthly attribution files and easy-to-read dashboards so practices can close gaps before year-end.

- **Make participation attractive.** Offer small-practice implementation support, user-friendly reporting tools, education on quality rules, and incentives—financial or Star-rating credit—for hitting digital-data milestones.

Implementing these steps transforms quality reporting from a retrospective paperwork exercise into a continuous, data-driven partnership—reducing provider burden, sharpening clinical decision-making, and improving patient outcomes.

Payers have a crucial role in simplifying clinical quality data responsibilities for providers. By implementing various strategies, payers can reduce the administrative burden on providers, enabling them to focus on delivering high-quality patient care. One key approach is to standardize quality measures, streamline data collection, and provide clear guidance on reporting requirements. This can be achieved through the use of automated data extraction tools, pre-populated templates, and standardized data formats such as the Quality Data Model (QDM).

Payers can also leverage existing data sources, such as claims data, to minimize the need for additional data collection. Furthermore, providing feedback on performance in a timely and actionable manner enables providers to identify areas for improvement and make data-driven decisions. By supporting provider-led quality improvement initiatives and encouraging collaboration between stakeholders, payers can facilitate the sharing of best practices and development of solutions to common challenges.

To reduce the administrative burden on providers, payers can develop user-friendly reporting tools, offer incentives for quality improvement, and support interoperability between different health IT systems. Additionally, payers can provide education and training on quality measures, data collection, and reporting requirements to help providers understand what is expected of them. By encouraging transparency in quality data reporting, payers can enable providers to compare their performance with peers and identify areas for improvement.

Payers have a critical role in simplifying clinical quality data responsibilities for providers. By implementing the strategies outlined above, payers can reduce the administrative burden on providers, enable them to focus on delivering high-quality patient care, and improve healthcare outcomes. By working together, payers, CMS, and providers can achieve a more efficient and effective healthcare system that prioritizes quality and patient care.

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?*

Payers and providers are increasingly interested in EHR technology that advances bulk extraction of clinical quality data from EHRs to payers. This interest is driven by several factors, including simplified quality reporting, improved accuracy, increased efficiency, enhanced analytics, better decision-making, reduced costs, and improved patient outcomes. By allowing payers to perform calculations using standardized algorithms and data validation techniques, bulk extraction of clinical quality data can improve the accuracy of quality measures and reduce the risk of errors. In addition to improved efficiency and reduced cost, payer-side processing further streamlines the data flow and reduces duplication of effort.

The benefits of bulk extraction of clinical quality data are numerous. It can simplify quality reporting for providers, reducing the administrative burden and minimizing errors. Additionally, payers can use advanced analytics and data visualization techniques to provide insights and feedback to providers, enabling them to identify areas for improvement and optimize quality performance. By having access to accurate and timely quality data, payers and providers can make better-informed decisions about patient care, population health management, and quality improvement initiatives.

However, there are also challenges and concerns associated with bulk extraction of clinical quality data. These include data standardization, data privacy and security, interoperability, and provider engagement. Ensuring that clinical quality data is standardized and formatted consistently across different EHR systems and payers can be a challenge. Furthermore, bulk extraction of clinical quality data raises concerns about data privacy and security, as sensitive patient information must be protected and transmitted securely.

Additionally, there are potential privacy concerns around the amount of data that is provided to a repository in which quality measures can run. Providers are hesitant to share more data than is minimally necessary (as required under HIPAA). So, ensuring there are clear specifications for the clinical quality measurements that outline which data fields are necessary and why, and any extractions of data are limited to the necessary sets of data, is an important consideration.

Another concern is the discrepancy across implementation guides that can change the data requirements from one use to another. This creates challenges regarding whether data content exists to populate the resource element required within the quality program. Just because there are standards-based definitions, does not mean EHR systems document and expose those elements within their HL7 FHIR Bulk Data Export payloads. An example of this would be regarding the inconsistent use of extensions as well as IG's requiring a different HL7 FHIR version than what the originating EHR supports.

Key challenges also exist in ensuring payers ultimately share reporting data back with providers in a timely manner, as well as providing transparency on how the calculations were performed and with what data, allowing providers to assess their progress with standard definitions and avoid costly surprises. In addition, shifting to payer-side processing can be made more effective by coordinating patient engagement across payers and providers.

Another key challenge arises when quality reporting is required at the network level, ACO level, or similar level instead of at individual healthcare facilities. Large health networks often rely on multiple EHR systems, making it difficult to generate a unified, longitudinal view of patient data. To address this, it is essential to first aggregate clinical data across disparate EHRs, creating a comprehensive patient record. Only after this aggregation can data be effectively exported in bulk to a measure calculation engine. Our findings underscore that cross-EHR integration is a critical first step to ensure accurate, network-level quality reporting.

To overcome these challenges, payers and providers are exploring various solutions, such as API-based data exchange, data normalization, data validation, and provider engagement and education. By addressing these challenges and concerns, payers and providers can ensure the success of bulk extraction of clinical quality data, leading to improved patient outcomes, simplified quality reporting, and increased efficiency. By working together, payers and providers can harness the potential of EHR technology advances to improve the quality and efficiency of healthcare.

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?*

The quality reporting and interoperability requirements faced by providers, whether for CMS or other payers, can be streamlined through standardization, data aggregation, and the facilitation of real-time data exchange. First, CMS and private payers should work adopt and maintain a unified, HL7 FHIR-based digital-measure library that references identical USCDI+ data elements and is certified by an independent body such as NCQA. When definitions and logic are consistent, a single standardized export from the EHR can satisfy all contracts, eliminating duplicate abstractions and bespoke code.

Payers can assume the analytic burden. By ingesting that shared export, enriching it with their own claims, pharmacy, and laboratory data, and returning refreshed scores and patient-level gap lists within twenty-four hours, they deliver timely clinical insight while sparing providers the expense of maintaining calculation engines. The same results flow directly into regulatory submissions and point-of-care alerts.
A uniform set of secure, HL7 FHIR-based APIs should replace today's assortment of proprietary portals and file uploads. With one credential and one connection, providers would receive current rosters, risk scores, and quality feedback, while payers automatically obtain new clinical information—without additional log-ins or manual transfers.

Finally**,** aligning all programs to a single annual reporting deadline, with optional quarterly submissions, would allow health systems to allocate resources once rather than managing multiple calendars. Taken together—shared measures, payer-run analytics, streamlined data exchange, and unified timing—these steps transform quality reporting from an episodic administrative task into a continuous, data-driven component of patient care.

6. *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?*

Looking at the data reported by ASTP/ONC website related to submission of information blocking claims, it does not appear that any of the information blocking claims that have been submitted were submitted by payers. There are 104 claims attributed to an unknown source, but none clearly attributed to payers. Based on this information, any claims submitted by payers would be an increase in claims.

CMS and ASTP/ONC could work to reach out to payer industry groups or payers in general through communication at various conferences and presentations. Most conference/webinar presentations focus on actors, compliance requirements, and the ability to file complaints, but do not venture into individuals and entities that CMS and ASTP/ONC are seeking to have submit complaints. By simply calling out payers in the description of the presentation and discussing their involvement with the exchange framework, including the need to file complaints, CMS and ASTP/ONC could see an increase in complaints filed by payers.

CMS and ASTP/ONC should also consider a blog on payer involvement in the data exchange ecosystem and why it is important for payers to participate, including filing complaints on potential information blocking violations.

We do believe that payers would offer a unique perspective on information blocking compliance and a differing set of circumstances under which actors may not be compliant with the information blocking requirements. There are already a substantial number of complaints filed by patients and a smaller, but significant number of complaints file by providers. As a result of this differing perspective, we do believe an increase in complaints filed by payers may result in some advancement of data exchange for the payment and/or healthcare operations use cases.

Section II.E – Technology Vendors, Data Providers, and Networks

Section 1 – Ecosystem

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?*

   As the largest payer in the world, CMS is uniquely positioned to be a catalyst for the future of digital health products, not only for their beneficiaries and their caregivers but for all US citizens. CMS should continue to accelerate the expansion of standards and mandates in data

modeling for exchange (e.g. HL7 FHIR) and clinical content (e.g. CQL) to reduce the barrier to entry for platform and application developers in building portable point solutions.

CMS could incentivize development in the digital health product space by offsetting potential app costs for patients and/or providers. This would help create a market for patient digital health products. CMS could also create a competition with potential awards like ASTP/ONC's Leading Edge Acceleration Project (LEAP). CMS could also look to contract with specific PHR apps or digital health products/tools for development or focus specific to what CMS wants/needs.

2. *Regarding CMS Data, to stimulate developer interest—*

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

   To strengthen data interoperability and improve care delivery, several types of additional data would be highly valuable if made available through HL7 FHIR-based CMS APIs (when applicable) through a single, unified API that supports patient-specific and bulk transactions:

   - **Comprehensive member-level data** that supports all CMS programs, such as:
     - Claim and Claim Line Feed (CCLF)
     - Beneficiary Assignment
     - Beneficiary Claims Data API (BCDA)
     - Data at the Point of Care (DPC)
     - TEAMS, MDS, OASIS, and IRF-PAI

   - **Clinical data from provider systems**, including structured EHR content like:
     - Encounters, lab results, assessments, and care plans

   - **CMS-derived datasets**, which provide essential context for care and population health management:
     - Chronic Condition Warehouse (CCW) indicators
     - Hierarchical Condition Category (HCC) risk scores
     - Geographic and socioeconomic indicators such as ZIP code-based deprivation indices

   - **CMS provider network data**, including:
     - Provider affiliations, specialties, physical locations, and plan/network participation.

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

Please refer to the response in subpart a of this question (2) immediately above.

c. *What obstacles prevent accessing these data sources today?*

Despite the growing availability of healthcare data, significant obstacles remain that limit its accessibility and usefulness. The current CMS data environment is highly fragmented, with datasets spread across multiple APIs that require separate credentials, endpoints, and data structures. This fragmentation, coupled with inconsistent implementation of HL7 FHIR standards, poses challenges for integration and scalability.

Further, many valuable datasets—such as HCC risk scores and CCW indicators—are not readily accessible via APIs and are often confined to static files or restricted-use formats.

Additionally, the lack of robust data provenance tracking reduces trust in aggregated data, while the absence of real-time or near-real-time data feeds limits the ability of providers to make timely care decisions.

Due to these limitations, there is a lack of patient-facing tools (like patient portals) that leverage these datasets to empower consumer engagement in their own health management, as well as proactive population level management capabilities.

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

To overcome current limitations and drive innovation, CMS and ONC should prioritize the development and support of a centralized, HL7 FHIR-based API platform that consolidates all CMS program data under a unified architecture.

This should include APIs that expose structured provider network information, such as affiliations, availability, and specialties—as well as access to CMS-derived insights like HCC risk scores and CCW indicators. Expanding API access to include socioeconomic and geospatial data, such as broadband availability or social vulnerability indices, would provide essential context for addressing health equity

and social determinants.

Additionally, APIs that enable patient engagement features, like appointment scheduling, care team messaging, and access to care plans, alongside real-time notification and subscription capabilities (e.g., HL7 FHIR Subscriptions) for all resources (not just ADTs) would significantly improve coordination and responsiveness across the care continuum.

Expanding on the library of APIs alone is not sufficient to easily scale connectivity. As CMS and ONC address national adoption of these APIs, TEFCA should be considered a central lever to enable rapidly scalable adoption under a common data sharing agreement and trust framework to quickly connect to the relevant APIs.

Section 2 – Digital Identity

3. *Regarding digital identity implementation:*

   a. *What are the challenges and benefits?*

When digital identity credentials are adopted at scale, they streamline the integration between patients, providers, and platforms by simplifying access and enabling cross system interoperability. This provides more real-time access to data across systems that can be used for longitudinal patient care.

A primary challenge to adoption is portability of an individual's digital identity between different providers. In today's landscape, patients have siloed identities between care providers and networks. While many vendors exist that would allow providers to accept high-assurance digital identities/credentials (for example: CLEAR, Login.gov, ID.me), there are non-trivial costs and effort in establishing business relationships with all such credential service providers. Ideally, a network might be created that offers providers access to all such credential service providers with reasonable and non-discriminatory terms, as to enable patients to use the credential service provider of their choice.

Other challenges include awareness of value, addressing perceived privacy risk concerns, and adoption (both by participating providers and patients). CMS is uniquely positioned to mandate the use of federated systems amongst contributing parties and can leverage that to educate and encourage adoption.

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?*

Requiring shared digital identity credentials—such as those aligned with NIST 800-63-3 IAL2/AAL2 standards—can significantly strengthen cybersecurity by reducing the attack surface associated with fragmented identity systems. A unified approach to identity enables tighter controls, improved auditing, and faster detection of suspicious activity, helping to mitigate risks like unauthorized access and data breaches.

In addition to security benefits, shared identity services play a key role in automated data exchange and dynamic data discovery across systems. They support the consistent and trusted identification of individuals across networks, which is critical for assembling longitudinal patient records from multiple sources, with various rights to scope of use. This creates new opportunities for real-time, context-aware access to health information, improving both care coordination and health outcomes. However, to achieve these benefits, a patient must be free to choose between these credential service providers when logging into their healthcare provider and/or Individual Access Services provider.

c. *What impact would mandatory use of the OpenID Connect identity protocol have?*

Mandating the use of OpenID Connect (OIDC) could drive greater standardization and security in identity management across healthcare. CMS could tie compliance to incentive programs or reimbursements, encouraging widespread adoption among providers. This would reduce fragmentation, streamline integration efforts, and enhance interoperability across systems.

However, requiring a specific digital identity solution—particularly one tied to a single credentialing provider or high-assurance verification process—may limit consumer choice and exclude individuals who are unwilling or unable to complete identity proofing steps. This could disproportionately affect vulnerable populations (many of whom CMS serves), such as the elderly, low-income individuals, or those without access to digital devices or broadband. It may also discourage the use of digital health tools due to perceptions of complexity, privacy concerns, or lack of trust.

While a mandate could bring technical and policy benefits, it would be important to balance those gains with flexibility in how patients are able to authenticate and access their health information in a way they trust.

Section 3 – Technical Standards and Certification

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

Considering the advances and challenges of the ONC Certification Program in combination with CMS' variety of incentive programs we urge both CMS and ONC to:

- **Provide time for the industry** - Collaborate to ensure timelines are always aligned to create a practical and manageable implementation program from software development to end-user utilization. Frequently timelines have been misaligned leading to either developer and/or providers not having enough time to respectively develop and implement.

- **Consider expanse of health IT ecosystem** - Consider all HIT necessary to enable the variety of APIs that need to be available consistently on both sides of the interoperability partners. With the HTI-2 NPRM ONC clearly recognized the need to describe the API's client and server side as to what the expectations are. CMS, as well as other agencies such as CDC, FDA, and others, can further support participation by incenting HIT other than EHRs to adopt the standards supporting those APIs. With CMS 0057 FR, CMS clearly recognized the need for payers to provide their side of the APIs. This similarly should be extended to other HIT such as laboratories, public health, and other relevant data holders.

- **Pilot standards, but only require mature standards** - Collaborate to ensure that standards have sufficiently matured before requiring adoption. We note the misalignment between CMS's 0057 FR and ONC's HTI-2 NPRM where CMS requires based standards in support of prior authorization and other APIs while recommending specific implementation guides for payers while ONC proposed to require not only the base standards (they were already required thus non-controversial) but also required the applicable implementation guides as well. This creates unnecessary asynchrony and friction.

  Considering the low maturity of the guides in terms of adoption and deployment at scale, we strongly support CMS' approach as it allows for a strong directional

statement yet allows for flexibility in the initial deployment phases without having strict certification tests to locked in versions that are not necessarily sufficient or correct. Proposing a functional criterion with similar recommendations would have provided clear alignment and direction.

We urge ONC and CMS to work closely with industry to establish a practical adoption approach that involve immature and not widely implemented standards that are seen as directional appropriate, but not ready for rigid testing regiments that inclusion certification program.

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?*

A nationwide provider directory, not limited to capturing HL7 FHIR endpoints but other endpoints and addresses relevant to recognized standards-based APIs (e.g., IHE Document Exchange APIs and DirectTrust Direct Secure Messages APIs) could provide immense benefit towards efforts to drive adoption of health applications. Seamless access to API endpoints/addresses, e.g., HL7 FHIR and IHE Document Exchange APIs, is effectively a pre-requisite to improving access to health information through health applications. Current state, certified health IT developers are required as part of the API Condition and Maintenance of Certification to publish lists of their customers HL7 FHIR endpoints used for purposes of patients accessing their health information (i.e., "patient-facing" HL7 FHIR-based API endpoints). While this requirement and the associated vendor publications provide benefit towards enabling patient-facing health app developers to better facilitate access for patients, there are a couple primary challenges that render this model non-ideal.

1. First, and most critically, asking vendors to maintain accurate endpoint metadata that is important for appropriately identifying the organization(s) and clinician(s) that each endpoint represents is a flawed approach. Vendors simply are not in the best position to populate and maintain the metadata (i.e., unique IDs, names, branding, etc.) for an endpoint that is used to apply meaning most accurately.

2. Second, individual vendor publications of endpoints still require consumers to retrieve from multiple disparate sources and consolidate.

Having the relevant addresses and endpoint maintained by the data holders themselves on their web sites (i.e., the healthcare provider, payer, or other actor), in combination with

directories maintained by networks who have a strong need to have them current and complete, e.g., TEFCA, DirectTrust, and HIEs, would enable the most robust and up-to-date directories in collaboration with the participating data holders to maintain the accuracy of the information and associated metadata in alignment with a standard – likely the HL7 FHIR User Access Brands and Endpoints. This would solve both dilemmas highlighted above but would also require some tangible incentive for those parties to contribute and maintain the information.

The best way to accomplish this would be to establish TEFCA as the centralizing source and incorporate it as a pre-requisite of connecting to the network, while TEFCA should consider making that directory available for uses outside of TEFCA as well, albeit without the benefits of all the other TEFCA capabilities

6. *What unique interoperability functions does TEFCA perform?*

TEFCA provides a valuable opportunity to take the next major step in advancing nationwide data exchange building on the learnings from its predecessors and other initiatives to enhance interoperability at a national level. Key capabilities for a national exchange framework that TEFCA addresses are:

- **A common agreement** – Sign once, connect under the same terms with all other common agreement signatories removing the many point-to-point data sharing agreements, enabling faster and broader reach.

- **A trust infrastructure** – Connect with every endpoint with a recognized token/certificate/other technology that the parties are operating under the same common agreement and are trusted. Have a shared identity management and matching approach to reliably link patients to their records across all data holders.

- **Record locator services** – Ability to identify with one query all the endpoints within the U.S. where a patient has data that can be shared, subsequently subject to having authorized access within applicable jurisdictional privacy rules and patients' data sharing rules.

- **Participant directory** – A shared directory of all participants, their roles, capabilities, and endpoints/addresses for the variety of technology used to share data and/or participate in workflows.

- **Governance, standards and operating procedures** – Governance, procedures, and technical standards for a wide range of APIs utilizing the most appropriate technologies and enabling the implementation and ongoing management of the

trusted exchange framework, and a neutral, final arbiter to resolve disputes.

These key capabilities facilitating the seamless exchange of EHI among more healthcare stakeholders, including patients across a wider set of exchange purposes.

Some of these elements are present in existing networks, frameworks, and collaborations. However, none integrate these at the national level in a comprehensive framework that enables participation by all across a growing set of use cases.

Exchange purposes initially are focused on the primary use cases for treatment, individual access, public health, payment, healthcare operations, and government benefits determination. While support for treatment has been the cornerstone for many networks and frameworks, also requiring support for individual access is a significant step forward enabling the patient to access their data and more fully participate in the coordination and delivery of their care. Projects are progressing to ramp-up public health and healthcare operations, after having had little traction in other networks even though available. Other exchange purposes such as research should be enabled as soon as possible considering the opportunities to more easily access relevant data across a wider community for patients participating in such research.

The initial API focus is on IHE Document Exchange, a well-established and mature API, ensuring continuity of data sharing under a single framework while building out the HL7 FHIR-based APIs that will substantially expand on the variety of use cases that do or do not need to depend on document representations of the data, rather just the data. This expansion will have significant value to all parties enabling rightsizing data access and drive consistency across all use cases that include the same data.

TEFCA empowers patients to access and control their EHI, promotes patient-centered care and management as well as population health across all healthcare participants, and ensures that EHI is formatted consistently, reducing errors and facilitating more accurate and efficient exchange of information. TEFCA's design allows for rapid scalability and flexibility, accommodating the diverse needs of various healthcare stakeholders, and enabling the integration of emerging technologies and innovations, going beyond current national frameworks. TEFCA enables a more connected, efficient, and patient-centered healthcare ecosystem, improving the quality and delivery of care. Further focus on provider, payer, and public health-centered APIs will continue to mature and evolve the efficacy of TEFCA across the entire enterprise.

Thus, while the actual utilization is still very limited, the foundation has been laid down to provide a more robust and comprehensive national framework than has been achievable to date.

Based on current industry trends and the complexity of implementing TEFCA we estimate that it will take the provider community approximately 12-24 months to fully migrate to TEFCA. This timeframe considers the steps involved from signing up to TEFCA through go live.

Oracle Health is committed to the success of TEFCA as also evidenced by its application to become a QHIN and is currently a candidate QHIN in the process of completing the important validation steps before it can be considered a designated QHIN.

a. *What existing alternatives should be considered?*

Several alternatives to the TEFCA exist to facilitate HIE at local, regional, and national levels. These alternatives include non-profit organizations, trade associations, and emerging technologies that enable secure and interoperable exchange of health information.

Regional or state-level HIEs facilitate the exchange of health information between healthcare providers, payers, and other stakeholders within specific geographic areas. Most are based on HL7 v2 and IHE Document Exchange based APIs, expanding into HL7 FHIR based APIs to enable secure sharing of health data. Organizations, such as the National Association of Health Data Organizations (NAHDO) and the Healthcare Information and Management Systems Society (HIMSS), provide resources and support for the development and implementation of HIEs.

For instance, DirectTrust, CommonWell Health Alliance, and eHealth Exchange are non-profit organizations that provide platforms for interoperable health data exchange at a national level.

At a national level a variety of alternatives exist. For instance, Civitas provides a Patient Centered Data Home approach to connecting HIEs nationally. DirectTrust provides a secure messaging network using the DirectTrust Direct Secure Messaging for exchanging mostly documents, but also event notification. CommonWell and eHealth Exchange of national networks that enable secure exchange of health information between healthcare providers, payers, and other stakeholders mostly

using IHE Document Exchange based APIs with HL7 CDA C-CDA document payloads, with some having started HL7 FHIR-based document exchange.

Many of these networks are further connected under the Carequality framework to provide a wider, national reach for data exchange under a common agreement, common exchange standards, and a common trust framework.

These alternatives to TEFCA may offer complementary or alternative solutions for healthcare organizations, depending on their specific needs and goals. However, for true nationwide data exchange to occur without friction a singular, common framework is essential that addresses the following capabilities:

- **A common agreement** – Sign once, connect under the same terms with all other common agreement signatories removing the many point-to-point data sharing agreements.

- **A trust infrastructure** – Connect with every endpoint with a recognized token/certificate/other technology that the parties are operating under the same common agreement and are trusted. Have a shared identity management and matching approach to reliably link patients to their records across all data holders.

- **Record locator services** – Ability to identify with one query all the endpoints within the USA where a patient has data that can be shared, subsequently subject to having authorized access within applicable jurisdictional privacy rules and patients' data sharing rules.

- **Participant directory** – A shared directory of all participants, their roles, capabilities, and endpoints/addresses for the variety of technology used to share data and/or participate in workflows.

- **Governance, standards and operating procedures** – Governance, procedures, and technical standards enabling the implementation and ongoing management of the trusted exchange framework, and a neutral, final arbiter to resolve disputes.

Alternatives being considered may have some of these capabilities, but not all for all exchange purposes currently in scope and being contemplated. Continuing multiple networks with different areas of focus, agreements, and standards would still require a national level framework enabling data to be shared easily across these networks.

TEFCA provides the next step towards this goal. This does not mean that TEFCA cannot be improved upon, but we can collectively advance TEFCA using these key capabilities as the foundation and expand from there. For example:

- Expanded purposes of use for research, and other emerging use case.
- Enable multiple technology options to advance different use cases towards common standards approach at each of the use case's appropriate pace.
- Transition funding and governance to a public/private approach.

Any alternative must address all capabilities identified above as seamless interoperability with high data fidelity and trust are must haves. Regardless of form, we always will have to work with all parties to make a national trusted exchange framework happen and see that as a common goal in the national interest of all patients.

b. *Are there redundant standards, protocols or channels or both that should be consolidated?*

There is redundancy that should be addressed, particularly considering the closed set of standards to be required. While generally appropriate, certain use cases can already benefit from TEFCA by the common agreement alone while operating with different technologies/standards. For example, eCase Reporting using IHE XDR and DirectTrust Direct Secure Messaging to communicate under Carequality/eHealth Exchange agreements, thus reducing number of data sharing agreements, yet building on existing capabilities, improving scalability. Another example would be the opportunity to align message standards where one can operate within and outside TEFCA consistently, DirectTrust Direct Secure Messaging vs. XCDR to aid in the migration towards HL7 FHIR-based messaging and notification once ready.

These can be addressed as TEFCA grows and expands by maintaining an open perspective on how best to advance national exchange where the starting point is based on the five essential capabilities of a national trusted exchange framework.

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

USCDI has, undoubtedly, improved interoperability and exchange of health information by providing a continuously expanding set of data, with EHI as a critical target, with associated vocabulary that defines the scope progression to drive support by defined standards (HL7 FHIR US Core and HL7 CDA C-CDA) and deployed through regulation, the ONC Certification Program in particular. At its root, USCDI is a mechanism for establishing broad data classes and elements that inform the scope of data that is expected to be sharable using recognized interoperability standards, particularly HL7 FHIR and HL7 CDA C-CDA.

This drives standardization for healthcare interoperability to provide a consensus framework through which to exchange and apply meaning to data so that it can be used more efficiently and effectively at the point of care. Without USCDI (and its predecessor Common Clinical Data Set and MU Common Data Set) providing a centralized scoping mechanism for standards to support and organizations to implement, we would not be where we are in healthcare interoperability.

In its current state, USCDI does have some limiting factors. These include:

- **Limited scope** – while USCDI is rapidly growing, it is still nowhere near addressing the full scope of data that would be considered EHI, plus other data critical to enabling interoperability. If we, as an industry, genuinely want to achieve effective interoperability of all EHI, then continuing to grow USCDI to gradually provide standards for representation of EHI will be important. Additionally, certain non-EHI to enable sharing of EHI needs to be standardized as well, e.g., directory data, standardized catalogs. We need to consider a mechanism to drive the necessary standardization in those areas as well.

- **Inconsistency with supporting standards specifications (HL7 FHIR + HL7 CDA C-CDA)** – USCDI defines data classes and elements as convenience groupings that do not build on the terminology of the standards that intend to support them. This creates ambiguities and challenges as to actual intended scope and how to properly represent that data in those standards. This leads to substantial efforts to translate USCDI into the supporting standard while still leaving ambiguity as to what data will actually be available when considering USCDI.

  We urge ONC to use HL7 FHIR elements sufficient to scope the data classes (resources) and data elements (resource attributes) with the relevant vocabulary (targeted value sets within the larger code systems) thus eliminating many questions of what the actual intent is, thus focusing further standards development on

completing all other aspects necessary to fully specify the interoperability requirements.

- **Frequency of updates** – there is a catch-22 here as the data set needs to be expanded to continue working towards encompassing all EHI, but frequent updates become difficult for developers to remain current with on an ongoing basis. Some of this can be remedied by amending the way USCDI is cited in certification program regulations to allow for developers to support only the USCDI data elements that they actively manage in their system, instead of having to support all.

- **Modularity of USCDI** – In the current state, HIT developers wishing to be certified for USCDI criteria are forced to support all USCDI data elements, whether or not they are actually relevant for their systems and customers. This will increasingly result in less HIT being able to be certified as one would have to support all of, e.g., the 170.315(g)(10) certification criterion's HL7 FHIR-based RESTful APIs to meet that criterion.

  To broaden the ability of more data holder to use certified HIT, thus create wider and more scalable access to patient data across all their data holders, we urge ONC and CMS to take a more modular approach to USCDI and certification criterion that enables HIT to be certified to the data they manage. Thus, a specialty her may not need to be certified to all USCDI yet still enables predictable access to data it manages. A health system wide EHR would typically certify to all USCDI, while an LIS would only certify to the data it needs to be able to share with providers, patients, and public health which would not include assessments and plans, care teams, and other data classes. Administrative HIT would address health insurance information and certain patient demographics, but none of the clinical data.

  We suggest that having HIT vendors attest to the data they manage and certify accordingly to the data they manage will provide a foundation to sufficiently challenge a party that has certified for less data than they manage to be accountable.

- **Limitations in scope of authority** – while ASTP/ONC has authority over EHR developers who certify their software to supporting recording and exchange of USCDI data, there are many other actors in the industry who hold EHI data that are part of USCDI's scope (either currently or in the future) who are not directly subject. For example, Picture Archiving and Communication System (PACS) vendors hold critical health data on behalf of healthcare providers but are not subject to certifying to

supporting USCDI and exposing data in accordance with corresponding data format standards.

The inability to effectively exchange imaging data creates significant barriers to timely and coordinated care, leading to increased healthcare costs due to duplicated tests and procedures. This inefficiency also places additional burden on both patients, who must undergo redundant imaging, and providers, who waste time trying to track down or re-order images, slowing down diagnoses and treatment plans. To truly achieve holistic standardization across the industry, there would need to be a carrot and/or stick applied to the broader set of data holders to coalesce around USCDI standards most EHR developers already have.

a. *Does it contain the full extent of data elements you need?*

As it stands today, USCDI does not contain the full extent of data elements needed to realize its full potential for the simple fact that it is still growing where it is our recommendation to eventually encompass what could be a common definition for all EHI and the foundation for any interoperability. This should not only by supported by HL7 FHIR-based RESTful APIs and to an increasingly lesser extent HL7 CDA C-CDA considering not all documents need to include everything always and HL7 CDA C-CDA documents is fully expected to migrate into the appropriate constructs in HL7 FHIR, but any interoperability standards for the data they support.

Note that a critical challenge is that different standards do not use the same vocabulary in all aspects apart from a core set. But even in the core set (e.g., SNOMED, LOINC, CPT4, ICD, etc.) ensuring that all standards use the same vocabulary for the same purpose is essential to maintaining high-fidelity interoperability throughout all data sharing transactions, regardless of standard used.

The current "ONDEC" process that USCDI follows for expansion provides a suitable path for continued necessary growth, including necessary transparency and collaborative opportunities for multiple industry stakeholders.

We want to call out the relationship between USCDI and the various USCDI+ domains have created confusion. This is due to a combination of factors:

- The absence of clarity on expectations to support USCDI+.

- Exchange of both USCDI and USCDI+ data cannot be expected to be limited to inclusion in HL7 CDA C-CDA documents and query-based HL7 FHIR-based RESTful APIs.

We suggest integrating USCDI and USCDI+ and use the categorization mechanisms introduced in USCDI+ to easily see what is in each version and what is in the base USCDI vs. USCDI+ domains, while at the same time including all data that is already shared using HL7 v2, NCPDP Script and X12 5010 recognizing how much data is already shareable.

We further suggest to use the current versioning of USCDI as the scoping mechanism for progressive adoption of HL7 FHIR (using HL7 FHIR US Core as the fundamental base) and stop using it for scoping further additions to HL7 CDA C-CDA documents as that only perpetuates to overload documents, rather begin to incent a further shift to using HL7 FHIR for general purpose data sharing and HL7 CDA C-CDA documents for actual documents until they can migrate to HL7 FHIR Documents.

We do want to clarify that integration of USCDI and USCDI+ as proposed must be done in conjunction with improved modular certification as suggested in our response to question 7 c) below to ensure that HIT is not certified to any more data than they actually manage.

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

The limitations in scope of data are not due to the definition of how it is utilized, but rather mostly related to the simple limitation in scope and format based on the relative infancy of the concept. As expressed above, this can be remedied organically by continuing to advance the data set following the "ONDEC" process, while switching to using HL7 FHIR elements as the expression tool for the data classes (resources) and data elements (attributes).

The one area that may be lacking is clarity on the long-term intent of the data set. As noted throughout this section, our expectation and recommendation is for USCDI to continue to grow and eventually provide a common definition of data classes and associated standards for all EHI. While there will always be some ambiguity and difference in interpretation, continued use to scope progressively expanded adoption

into applicable interoperability standards this is an appropriate goal that the USCDI is well-positioned to serve.

Expressing that intent for clarity to the industry and using it as a guiding light for the gradual annual expansion would be a helpful step from ASTP/ONC.

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

Adding more data elements will naturally involve challenges as it means impacted parties (health IT developers, healthcare providers, etc.) need to react and invest in aligning with it. However, using a modular approach on requiring USCDI as described in our introductory response to this question (question 7), this is a necessary and acceptable burden to carry for moving the industry forward (i.e., this burden can be reduced is to amend the way USCDI is cited within the Health IT Certification Program by allowing certified health IT developers to certify to only the scope of USCDI data elements that their system actively manages). This will alleviate the need for systems to develop and maintain support for data that their customers do not have a distinct need for, which significantly contributes to the burden today.

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

While LLMs and other AI have the potential to completely change the way we think about data processing and enabling data to empower clinicians, they will not completely replace the need for standards. Rather, the immediate value they can provide is in the ability to seamlessly interpret standardized unstructured and non-codified data at time of data collection and documentation or time of ingestion for use in a meaningful manner.

Therefore, instead of abandoning the structured data formats that have become well established in health IT, we should seek to harness the power of AI to better align data to those structured formats and leverage them as part of machine learning to do more for clinicians at the point of care. For example, fully automating clinical reconciliation processes to relieve clinician burden and time spent away from the bedside, or leveraging rich, fully structured data to provide better insights and support for clinicians alongside of unstructured notes, images, and other relevant data.

We further note that structured and standardized data, where easily available, e.g., laboratory results, assessments, plans, etc. still enable more accurate interpretations than if they were reverted back to unstructured narrative text where it is subject to more variations and therefore more interpretation. We suggest therefore that we should continue to structure and standardize where we reasonably can, while expanding the use of unstructured data such as notes to gain a more complete insight into the full data set. I.e., add AI and LLM to the toolkit, but do not replace per se what can be more naturally structured and take advantage of both types of data.

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

There are many areas of the program that have provided substantial benefit to the industry. In many ways, the program is what not only drove the digitization of healthcare but also drove the acceleration of nationwide interoperability in the industry.

The starting point which has always provided a key foundation for the program are the Privacy & Security criteria under 179.315(d). These criteria are rooted directly in the HIPAA Security Rule's technical safeguards (along with some HIPAA Privacy requirements) and provide the closest thing to a recognized certification for HIPAA Security. The Privacy & Security framework continues to provide meaningful value and is critical to maintain as a core feature of the program but is due for expansions and strengthening of requirements to maintain currency with modern security standards and best practices. For example, incorporating identity federation capabilities into the 170.315(d)(1) criterion or delving further into data segmentation and consent modeling.

In the earlier stages of the program, criteria for Transitions of Care (170.315(b)(1)), View, Download, and Transmit to 3rd Parties (170.315(e)(1)), and Direct Project (170.315(h)(1)/(2)) provided the most meaningful value by establishing HL7 C-CDA document-based interoperability as a critical interoperability standard and secure Direct messaging as the primary method for treatment-based data exchange amongst healthcare providers. However, we have since graduated to a focus on more flexible and capable HL7 FHIR-based API-based interoperability starting with greenfield use cases such as RESTful query-based access to complement document-based exchange, and subsequently replacing HL7 CDA based documents with HL7 FHIR based documents for increased consistency across interoperability paradigms.

As mentioned immediately above, the criteria that have provided the most tangible value for the industry in recent years has been the RESTful API-focused criteria, beginning with the standards-agnostic criteria adopted with the 2015 Edition of the program and advancing into the HL7 FHIR-based Standardized API for Patient and Population Services criterion today. We hope and expect that the program will continue to emphasize standardized API-based capabilities to continue to build upon the foundation that has been established, considering HL7 FHIR-based APIs for greenfield use cases to start and appropriate migration from classic standards-based APIs to HL7 FHIR-based APIs.

However, critically, this needs to be done sensibly by focusing on letting the market drive priorities and incorporate new standards and requirements into the program when there is both (1) a sufficient level of maturity for the standards (e.g., published implementation guides with easily referenceable successful real world implementation) and (2) a clear and specific use-case for the standard (i.e., avoiding adopting standards without a use-case to drive its utilization).

Finally, public health criteria – most specifically those for Immunizations (170.315(f)(1)), Syndromic Surveillance (170.315(f)(2)), Electronic Lab Results (170.315(f)(3)), and Electronic Case Reporting (170.315(f)(5)) – have provided immense value in standardizing the process of critical reporting to public health agencies (PHA). However, there is still opportunity for improvement, most specifically in the current model under which certified health IT developers and their healthcare provider customers are held to utilizing specific standards while PHAs are not. This is a model that was proposed to be changed with the proposals for recipient criteria in the HTI-2 proposed rule, which would be a welcome development.

9. *Regarding certification of health IT:*

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

        Focusing the future of the certification program on interoperability, taking advantage of a variety of API approaches, considering advancements in classic standards-based APIs and adoption of HL7 FHIR-based APIs, using suitable pull/queries-based and push/messaging approaches, is undoubtedly the correct approach and mindset. This is where regulation can make a meaningful difference while maintaining necessary flexibility and autonomy for developers to design their products and internal functionality to the needs and desires of their customers.

Also, as referenced in previous comments, shifting focus away from using document-based exchange for essentially large data set (particularly HL7 CDA C-CDA CCD documents that typically are large data sets in a document envelope) and towards HL7 FHIR-based APIs enabling sharing of large data set, which still support documents where appropriate, is also key in order to continue pushing interoperability forward and making data exchange more seamless, efficient, and purpose-specific.

We note that while prioritizing API-enabled capabilities one must also prioritize privacy and security to ensure interoperability occurs in a trusted and secure environment in accordance with the applicable jurisdictional privacy rules and a patient's data sharing consent directives.

We also suggest clarifying that API-enabled capabilities are not limited to "HL7 FHIR-based RESTful query APIs." Certification should be interoperability focused and consider the relevant and appropriate APIs that need to be supported at scale. That includes HL7 v2 based APIs, and NCPDP SCRIPT based APIs, and other forms of APIs fit for purpose. Not just RESTful APIs, or just query based APIs. "API" must be interpreted in its fundamental meaning and be constrained only to being open standards-based for purposes of certification – not exclusively "HL7 FHIR-based RESTful API queries."

b. *What would be the drawbacks?*

Considering the reference to "API-enabled capabilities" is likely intended to specify HL7 FHIR-based standard RESTful query API functions then it is important not to scrap current criteria that are valuable in their current form just because they are not HL7 FHIR-enabled as indicated above. For example, public health reporting via HL7 v2 or HL7 CDA-based standards largely function well across the country today and are also APIs.

Where adding data requirements are more easily addressed by updating those guides than full replacement with a HL7 FHIR-based approach we should not prematurely force a change. Conversely, the necessary additions may not be well suited anymore using classic standards and it is time consider the shift to HL7 FHIR-based reporting, e.g., syndromic surveillance requirements for more clinical data in the message may necessitate an earlier change to HL7 FHIR-based reporting. Thus, there is no reason to remove such criteria from the program.

Rather, maintain what works and build upon what there is already recognizing that HL7 FHIR-based APIs, whether using RESTful technology or in messaging paradigms (e.g., HL7 Bidirectional Services eReferrals HL7 FHIR implementation guide), represent the logical progression for green-field use cases and longer-term replacement of existing, "classic" APIs.

Additionally, as alluded to in the above response in regard to secure and trustworthy interoperability, the program needs to maintain its foundational components, such as the Privacy and Security framework and functional criteria which align directly with a statutory requirement. In other words, the program can never be strictly a set of HL7 FHIR-based RESTful API criteria and requirements. The program should consider the variety of open standards-based APIs to drive and expand increased interoperability.

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)?*

We note that free text, pdfs, and other unstructured data can already be accessed using HL7 FHIR based APIs, but also be included in "classic" APIs. For example, Advanced Directives, mostly available in .pdf files or scanned are addressed in USCDI v5, supported in HL7 FHIR US Core v7 that is approved for SVAP and in line to be adopted in a next certification regulation. USCDI could be adjusted to clarify other types of scanned and free text of interest, such as proposed for USCDI v6 for Portable Medical Orders that initially would typically only be available as scanned documents and .pdf files. HL7 FHIR DocumentReference would be the suitable format for HL7 FHIR-based APIs to expose such data.

While free text, pdfs, and other unstructured can be exchanged, we need to be cautious that is not a reason to not drive for migrating to structured representation wherever possible, e.g., Advanced Directives having the ability include computable directives rather than free text instructions requiring interpretation.

ONC could utilize more robust test data sets that include the data of interest validating that such data can be shared according to the appropriate API, while continue to work with industry to identify standardized, structured data wherever appropriate.

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?*

We note it to be important to distinguish between making data widely available through query-based APIs vs. sharing data using push-based APIs. The first raises concerns of performance (being accessed at any time at any frequency, potentially impacting operational performance of critical systems forcing deployment secondary use systems to reduce these risks at a cost), as well as dynamically managing minimum necessary data requests by authorized parties. The second raises concerns about timeliness and completeness.

We suggest that there is not a single approach that should be pursued, rather both can enable a learning system to find the appropriate balance between either that can best support the use case needs balancing these conflicts.

Separately, it is worth noting that the policy and regulatory mechanisms to motivate providers to respond to authorized requests for data largely exist already via Information Blocking regulations and certified health IT data exchange standards – the latter of which are incorporated into the former by way of recommended formats for exchange when a format specified by the requestor cannot be supported. Similarly, participation in programs involve minimum reporting requirements that can drive sharing relevant 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?*

Bulk HL7 FHIR holds significant promise as a standardized approach for transferring large, multi-patient datasets across diverse healthcare scenarios while maintaining data fidelity. As digital quality measures (dQMs) take hold, and where needed inclusion of underlying source data, bulk HL7 FHIR allows for efficient data exchange by enabling comprehensive, population-level data retrieval in a single exchange, reducing repeated queries to source systems and supporting scalable, efficient data workflows.

However, bulk data requests still place substantial demands on health IT infrastructure of EHRs that are primarily optimized for clinical documentation and real-time workflows—not high-volume data export. Requiring EHR systems to

handle frequent or large-scale bulk data operations can degrade their performance and impact clinical availability.

To mitigate this, flexibility is needed to allow the use of secondary data platforms for these purposes —such as health data intermediaries or population health tools—that are architected for large-scale data exchange without compromising EHR operations.

Additionally, even with widespread use of bulk HL7 FHIR, CMS would require a repeatable process for data retrieval across contributing health systems that can normalize across varying HL7 FHIR implementations without added burden on the provider's systems. A consistent approach for communicating patient attribution is also critical to enable correct data retrieval and inclusion for quality measure programs.

Lastly, privacy and security concerns should be considered in determining when to share the underlying source balancing the benefits and risks between distributed data analysis by the sources vs. centralizing the analytics.

At CMS' scale, unlocking the value of bulk HL7 FHIR for quality submission will require coordination with data producers (EHRs, Payers, etc.) and their software vendors to make data available. A strong technology company, like Oracle Health, will be a key relationship in collaborating with CMS and this broader community to push the necessary advances across the ecosystem (centrally or otherwise).

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 certificahern (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?*

Considering the responses to prior questions we suggest that ONC:

- Use the full toolbox of open, standard APIs, while using HL7 FHIR based APIs (query, push, message, subscription, or otherwise as appropriate) as the general go-forward direction for greenfield and longer-term replacement of "classic" APIs to align on syntax and format, using transport and interaction paradigms as appropriate for the use case at hand (i.e., not just HL7 FHIR-based RESTful query APIs only).

- Use a modified USCDI based scoping approach, as described in our response to question 7 of this section, to drive iterative expansion of interoperability capabilities over time.
    - Merge USCDI and USCDI+ into one data set that can be filtered by domain and relevant standards/implementation guides that support using versioning to drive iterative scope.
    - Use HL7 FHIR elements as the modeling language for data classes (resources), data elements (attributes) and vocabulary (bindings).
    - Include all data classes and elements that are already present in standards and implementation guides used in ONC's Certification Program.
- Recognize the need to include all health IT supporting data holders where EHI is managed.
    - Enable and incent certification to both the client/receiver and server/sender side of the API.
    - Enable modular certification to the scope of data the health IT actually manages without requiring systems to manage data the health IT's target users do not need to be managed.

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?*

    Yes. EHI Export, in its current form, has not achieved its goals of simplifying patient access to their full heath record nor streamlining the process of providers switching health IT systems. There are numerous variables contributing to this, but chief amongst them is the lack of defined standards – both for the data format and the delivery mechanism.

Although developers must publish their specifications publicly to support consumers' ability to understand and process their proprietary exports, healthcare data is complex and challenging to accurately interpret void of common and well-understood standards that all sources adhere to. This is true regardless of how detailed and thorough a developer's format specification documentation is. Furthermore, particularly in the case of the patient population export, the volume of data involved makes it unrealistic to expect that an export can truly be processed and migrated in a seamless and efficient manner without significant human resource dedication.

Considering the need for standards, we recommend that the EHI Export criterion changes focus form all EHI to all USCDI and references guidance on how to support EHI Export using HL7 FHIR Bulk Data Export that includes an organized USCDI data set. We suggest that EHI Export be repurposed considering these realities and scope to a HL7 FHIR-based data set that can be shared using HL7 FHIR Bulk Data Export for a single or multiple patients that contains all USCDI scoped data as expressed in HL7 FHIR US Core, and that can grow not only based on HL7 FHIR US Core expansion (which is only a limited data set) but on an identified combination of HL7 FHIR US Core and profiles from implementation guides reflecting specialized data such as full laboratory results, care plans, and other full data sets.

Any data not yet available in HL7 FHIR format would require special effort by the receiver, even with all the technical specifications describing the data sets. Additionally, the purpose should not be for HIT-to-HIT migrations as those typically require much more tailored solutions where a base standardized set would not be enough. In effect, EHI Export would be re-defined as an HL7 FHIR Bulk Data Export use case with a targeted implementation guide.

With repurposing the EHI Export to an HL7 FHIR Bulk Data Export based criterion that will also allow for the removal of the bulk data requirements from 170.315(g)(10) consolidating bulk data capabilities into one, modular requirement that may be satisfied by appropriate HIT best suited to support such bulk queries. We recognize the concerns of EHR performance for certain bulk data volumes when exercised. Having a modular approach that enables HIT to support the requirements which could be the EHR for certain bulk data use cases but not others or even none enabling optimum use of technology necessary to support these use cases. Additionally, it enables advancement of use case specific implementation guides addressing specific requirements and capabilities, including where necessary relevant SLA measures.

b. *Are there specific workflow aspects that could be improved?*

The workflow aspects of EHI Export are not where the issues lie. In fact, imposing specific workflow requirements as part of the criterion would likely impose new challenges. Instead, the focus should be on re-positioning requirements around standardized data formats and exchange methods.

c. *Should CMS consider policy changes to support this capability's use?*

Given that EHI Export capabilities are intended for use in reaction to a specific situation or request – i.e., they are likely only used if/when a patient requests an electronic and computable copy of all their EHI or when a provider decides to transition health IT systems – it would not be sensible for CMS to adopt requirements that would mandate its use by healthcare providers. If the capability does not provide distinct value above other available mechanisms for the defined purposes (i.e., enabling patients electronic access to their health records and facilitating transitions to new health IT systems for providers) then there is no reason to force its use.

Instead, as expressed in responses to the previous questions above, it is far more sensible for the industry to re-position around standardized data exchange HL7 FHIR with guidance for its specific use case such as being advanced for UDS+ and Immunization Bulk Queries. While the scope of data that is established for standardized exchange via these mechanisms does not fully account for all EHI held in health IT systems, experience suggests that it successfully serves the vast majority of needs and use-cases. And for those instances where a fuller set of data is needed, customized approaches can currently satisfy needs until a point in which USCDI is able to truly encompass "all EHI."

Section 4 – Data Exchange

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

We understand "endorsement" of non-CMS data sources and networks to imply a form of formal recognition—akin to a certification, even if more streamlined than current models. For this, CMS should establish clear, consistent criteria that all participating health IT actors must meet to be considered trusted contributors to its programs.

These criteria should include demonstrated conformance to relevant technical standards (e.g., HL7 FHIR, X12, QRDA), validated through scalable testing mechanisms; strong data quality

and governance practices; robust privacy and security safeguards; and alignment with patient-centered outcomes. Participation in national frameworks such as TEFCA should be considered a key pathway to meeting these expectations, as it provides a common trust fabric and operational baseline for interoperability.

The goal is to ensure a level playing field where all data holders and networks are held to the same minimum bar. This fosters trust, predictability, and accountability across the ecosystem—giving stakeholders confidence in the data being shared and used. With that foundation, participants can focus on innovating and competing to improve care, outcomes, and system efficiency.

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

APIs granting access to the entirety of a patient's EHI present transformative opportunities—particularly as enablers of intelligent, agentic systems. These APIs are not just about data access for human users, but about powering next-generation tools (and even medical devices) that can reason, act, and coordinate care autonomously. Agentic AI systems, for example, can use APIs to surface insights, manage workflows, personalize care, and interact across systems on behalf of patients, clinicians, and administrators.

While recent focus has been on HL7 FHIR-based RESTful query APIs, it is important to view APIs more broadly. Interoperability has long been driven by APIs—batch, event-driven, service-oriented, and more.

The adoption of HL7 FHIR-based APIs adds a new, flexible substrate for modern interoperability, not limited to query-based models. HL7 FHIR-based APIs support diverse interaction patterns (e.g., RESTful queries, subscriptions, bulk data access), allowing tailored solutions for everything from real-time clinical decision support to population-level analytics.

With expanded EHI access, we unlock not only patient-facing innovation—such as richer apps and better health engagement—but also the development of advanced tools for research, operations, and care delivery. This new class of APIs shifts the focus from just "sharing data" to enabling intelligent action, coordination, and personalization at scale.

a. *What are the primary obstacles to this?*

Unlocking the full potential of APIs that provide access to a patient's complete electronic health information (EHI)—especially for enabling intelligent, agentic systems—faces a range of social and technical challenges.

First, not all data providers have been incentivized to implement comprehensive APIs, and many lack the business drivers or regulatory mandates to prioritize them. As a result, API adoption across the healthcare ecosystem is uneven, and large swaths of EHI remain inaccessible in practice.

Second, the pursuit of longitudinal data standardization has been slow. The fact that we are still evolving through multiple versions of USCDI illustrates how far we are from mandated, standardized, computable representations of a full longitudinal record that accommodates critical ancillary concepts like social determinants of health (SDoH), genetic data, and wearable device data, and more. Agentic systems depend on ubiquitous, high-quality data, but variability in data definitions, vocabularies, and availability across systems limits automation.

Third, many current APIs are not designed for machine orchestration. To support intelligent workflows, we need APIs that go beyond read access—supporting write operations, real-time subscriptions, task automation, and granular permissions frameworks to enable delegated activity by systems acting on behalf of users.

Fourth, the infrastructure to support continuous, scalable, modern AI-enabled environments is not ubiquitous. Unlike Oracle Health, most health IT environments are not optimized for the performance and orchestration demands of agentic systems, and few support the underlying hyperscale hardware needed for these modern architectures.

Finally, the cultural, governance, and trust frameworks have not caught up with technical capabilities. Many healthcare organizations are hesitant to bring in more health data than is necessary in a world of information blocking. The storage of a longitudinal health record raises concerns around when that data becomes part of the organizations medical record for the patient, liability concerns around data not captured by the organization itself or that has not fully been reviewed by one of the organizations own clinicians, and concerns around the accountability to produce all that that information upon request under HIPAA and considering information blocking disincentives. Additionally, delegating actions to intelligent systems raises unresolved questions about accountability, liability, and consent. Without a shift in

mindset and policy to accommodate this new model, adoption will remain limited.

Ultimately, realizing the promise of comprehensive EHI APIs for intelligent care requires ongoing collaboration between policy makers, health care providers, and technology vendors to reduce these social and technical barriers and ensure broad EHI API plays a key role in the next generation of personalized health care.

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

As we note in our response to question 7 in Section II.E Section 3 Technical Standards and Certification, we recommend that USCDI evolves to encompass EHI and that USCDI and USCDI+ domains are managed together as one. Such an approach recognizes there is no trade-off as in the end we have to arrive at having agreed to standards for all EHI, including how to include unstructured data.

As further outlined in the response to question 7, enabling a modular adoption approach considering that HIT that does not manage all data in HIT, use cases and HIT capabilities will determine when to share what subset of USCDI in accordance with applicable standards, thus creating a more efficient and targeted adoption of USCDI across all participating HIT.

14. *Regarding networks' use of FHIR APIs:*

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?*

Our network is connected to over one million endpoints, including hospitals, health systems, medical groups, pharmacies, laboratories, and other healthcare organizations. These endpoints are connected through various interfaces, such as HL7 v2, HL7 FHIR, and other APIs, enabling seamless data exchange and interoperability. The network covers a wide range of endpoint types, including provider organizations, payer organizations, pharmacies, laboratories, and medical devices.

The network spans across various geographies, including all 50 states in the United States and international locations such as Canada, Europe, Asia-Pacific, and Latin America. Our directory services provide real-time access to provider information, including searchability by National Provider Identifier (NPI) or organizational ID.

Additional features include endpoint validation, data standardization, and robust security measures to ensure compliance with industry standards, such as HIPAA and ICD-10. With its extensive network and advanced features, Oracle Health is ideal for patient data sharing needs and is committed ’o supporting organizations' goals through seamless interoperability.

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

Oracle Health’s connections are established through a combination of industry-standard interfaces and protocols. We utilize various methods to establish these connections, including HL7 FHIR 170.315(g)(10) endpoints, IHE XCA, and proprietary APIs. HL7 FHIR-based connections enable standardized data exchange and interoperability with healthcare organizations, while IHE XCA protocols facilitate the exchange of clinical documents and medical information.

Additionally, we develop and utilize proprietary APIs to connect with endpoints that require customized integration, ensuring seamless data exchange and interoperability. We also support other industry standards, such as HL7 v2 messaging, DICOM for medical imaging, and NCPDP for pharmacy transactions.

The connection establishment process involves several steps, starting with initial engagement with the endpoint organization to discuss their specific connection requirements. A technical assessment is then conducted to determine the feasibility of the connection and identify potential integration challenges.

Next, we develop and configure the necessary interfaces, including HL7 FHIR endpoints, IHE XCA, or proprietary APIs in non-production environments where possible. Thorough testing and validation are performed to ensure the connection is secure, reliable, and compliant with industry standards.

Finally, the connection is deployed to production, enabling seamless data exchange and interoperability between the endpoint organization and our network. We are also committed to integrating with TEFCA, enabling secure and standardized data exchange between healthcare organizations.

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

Oracle Health does interconnect with other networks to facilitate the secure and seamless exchange of healthcare information. We support interoperability under various frameworks, including CommonWell, Carequality, and eHealth Exchange at a national level, numerous HIEs, while we are in the process of becoming a QHIN through our Oracle Health Information Network (OHIN).

We establish private agreements with other networks and healthcare organizations to enable the exchange of health information, and support various HL7, NCPDP, and X12 standards for the exchange of clinical, administrative, and financial data between healthcare applications. Additionally, we are a member of DirectTrust, a non-profit organization that promotes the use of Direct messaging for the secure exchange of health information and provide a HISP to enable exchange of Direct message.

By supporting these frameworks, networks, and standards, including TEFCA, private agreements, HL7, NCPDP, X12, and DirectTrust, Oracle Health enables the secure and seamless exchange of healthcare information, promoting interoperability and improving the quality of care. Our solutions are designed to facilitate the secure and reliable exchange of health information, and our HL7 FHIR-based APIs enable the secure and standardized exchange of health data, promoting interoperability and facilitating the development of innovative healthcare applications.

15. *Regarding bulk FHIR APIs:*

    a. *How would increased use of bulk FHIR improve use cases and data flow?*

    HL7 FHIR Bulk Data Export holds significant promise as a standardized approach for transferring large, multi-patient datasets across diverse healthcare use cases. One of its key advantages is the ability to access a broad spectrum of clinical data for patient cohorts without compromising data fidelity.

    As the adoption of digital quality measures (dQMs) accelerates, and as new HL7 FHIR resources and data elements are introduced to support evolving measure logic, the pressure on data acquisition and exchange mechanisms continues to grow. HL7 FHIR Bulk Data Export addresses this challenge by enabling comprehensive, population-level data retrieval at the point of exchange—reducing the need for repeated queries to source systems and supporting more scalable, efficient data workflows.

    b. *What are the potential disadvantages of their use?*

HL7 FHIR Bulk Data Export can be expensive to operate and may fall short of performance expectations due to the substantial data volumes often involved. Under the current model—driven b' HL7 FHIR Bulk Data Export's inclusion in the CEHRT definition, these APIs are typically implemented directly on top of EHR systems. This architecture increases the risk of degrading EHR system performance, potentially impacting the delivery of direct patient care, which is the EHR's primary function.

Maintaining HL7 FHIR Bulk Data Export implementations also poses challenges. Patient cohorts or groups must be continuously updated to ensure that the correct population is being exported for each specific purpose, adding operational complexity. These challenges should not deter the continued development and support of HL7 FHIR Bulk Data Export as a standard. Instead, they underscore the importance of thoughtful policy and regulatory design.

To fully unlock the potential of population-based HL7 FHIR Bulk Data Export, broader adoption of event-driven push or subscription-based notification mechanisms, should be prioritized across all resources. Use of other HIT to enable bulk data sets from EHRs to the intended endpoint could isolate EHRs from the impacts of direct HL7 FHIR Bulk Data Export. These approaches can significantly reduce operational overhead by improving data timeliness and eliminating the need for repeated, large-scale data pulls—thereby enhancing efficiency and reducing cost.

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

The tradeoffs between point-to-point models and shared network infrastructure can be broken down into four key areas: technology, support, speed to value, and speed to innovation. In terms of technology, point-to-point models require customized integrations, leading to higher costs, increased risk of errors, and limited scalability. Conversely, shared network infrastructure provides a standardized framework, enabling greater and faster scalability, improved data consistency, and reduced costs.

When it comes to support, point-to-point models require specialized expertise, resulting in higher support costs, increased downtime, and limited visibility into system performance. In contrast, shared network infrastructure offers centralized monitoring and management capabilities, improved visibility, and reduced support costs. This approach allows for more efficient and effective management of system performance and issues.

In terms of speed to value, point-to-point models can provide rapid solutions for specific business needs but can also lead to longer-term integration challenges and technical debt. Shared network infrastructure, while requiring more upfront investment, can provide faster time-to-market for subsequent projects, improved agility, and reduced overall costs and complexity over time. This approach enables organizations to respond more quickly to changing business needs and drive greater value.

The speed to innovation is also an important consideration. Point-to-point models can hinder innovation by creating technical debt, limiting future flexibility, and inhibiting the adoption of new technologies.

In contrast, shared network infrastructure can accelerate innovation by providing a flexible and scalable foundation for new technologies and services. This approach enables the rapid integration of emerging trends and innovations, fostering a culture of collaboration, standardization, and reuse.

While point-to-point models may offer short-term benefits, shared network infrastructure provides a more sustainable, scalable, and innovative approach to integrating systems and driving business value. By adopting a shared network infrastructure, organizations can reduce costs, improve support, and increase their speed to value and innovation, driving greater success and competitiveness in the market.

a. *Do current rules encourage scalable network participation?*

   While current rules encourage performance-based collaboration across systems, network-based interoperability is not enforced and incentives around data-sharing are lacking, thus limiting the full potential of network participation and scalability. There needs to be direct incentives related to data sharing and adoption of shared network infrastructure to better promote interoperability and overall network participation.

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

   Several changes can be made to improve alignment, including standardizing APIs, implementing reciprocal access, and establishing common data standards. API unification, for instance, would facilitate seamless integration and enhance interoperability by adopting industry-standard APIs or developing a unified API

framework. This, in turn, would enable effortless communication between disparate systems.

Additionally, reciprocal access mechanisms, such as trust frameworks and data sharing agreements, would allow for mutual exchange of data and services, promoting collaboration and reducing barriers to information sharing. We recognize the challenge that reciprocal exchange still involves cost on both sides of the exchange. Where the value and volume are not sufficiently aligned and symmetrical across both sides careful consideration must be given to how cost is distributed in an equitable fashion.

Implementing interoperability frameworks and collaborative governance models can also improve alignment. Interoperability frameworks would provide a structured approach to integration, outlining clear guidelines and specifications for data exchange, service interfaces, and security protocols.

Collaborative governance models, on the other hand, would facilitate joint decision-making and promote a culture of cooperation among stakeholders. This can be achieved through joint committees, working groups, or other collaborative structures. Furthermore, establishing common data standards, such as standardized data models and taxonomies, would enable effortless exchange and interpretation of data across different systems.

By implementing these changes, organizations can improve alignment, enhance collaboration, and reduce barriers to information sharing. This can be achieved by also focusing on security and trust, as well as change management. Implementing robust security measures, such as standardized security protocols and encryption technologies, would ensure the confidentiality, integrity, and availability of data and services shared across different entities.

Effective change management processes would also help stakeholders adapt to changes, minimizing disruption to existing operations and maximizing the benefits of enhanced collaboration and integration, leading to more efficient, effective, and innovative operations.

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?*

Considering the critical need for a national exchange framework that enables nationwide access across all relevant health stakeholders, we see an important role for both ONC and CMS to support in the initial funding and governance of such a framework while providing incentives in various forms to for health data holders to join that framework. We support TEFCA as the next generation of such a framework.

We note that initial funding is of particular importance as we will effectively have two national frameworks in operation at the same time, having an increased burden to support such a migration, while over time funding can mostly be shared across the participants. Considering resources of many health data holders it will be important to identify funding enabling as many as possible to join.

Lastly, considering the importance of trust, as part of essential participation in governance to manage a critical national infrastructure, there is a need for clear a clear and final arbiter for participation in specific exchange purposes in accordance with HIPAA.

Section 5 – Compliance

18. *Information blocking:*

    a. *Could you, as a technology vendor, provide examples for the types of practices you have experienced that may constitute information blocking. Please include both situations of non-responsiveness as well as situations that may cause a failure or unusable response?*

    Oracle Health is aware of several practices that potentially amount to information blocking. For example, certain health IT vendors cite protection of Intellectual Property (IP) as a reason not to engage in information exchange with competitors or with healthcare entities that contract with competitors. Where we have seen or heard of this practice, however, IP pretexts have appeared specious and likely designed instead to stifle competition. Similarly, certain health IT vendors overly restrict how and how often they will share their client's data in response to legitimate requests from competitors, even when their clients want to share such data more frequently or in a different manner. In these instances, we have seen or heard about the health IT vendor claiming potential performance issues that may result if information is shared in the manner requested, without providing any substantive evidence in support. We would encourage more active investigation and enforcement of the information blocking provisions in the law to address these concerns.

On the other hand, we have also seen the information blocking rules be used as a tool against health IT vendors that are trying to follow the law in good faith. Hospitals and health systems that refuse to pay bills is an increasing problem for health IT vendors. These customers know that information blocking provisions in the law make it difficult for a vendor to terminate services in response to nonpayment, because of the requirement to continue to provide customers access to their data. This results in many customers taking advantage of the situation by refusing to pay and even refusing to enter into payment plans for their Health IT services.

Transitioning between EHRs can take 18 months to 2 years, so efforts to terminate a contract can take over 2 years to ensure clients have enough time to transition to a new system and take their data with them. This is a significant burden for vendors to shoulder without payment, and ultimately just hurts patients because it drags resources away from improving our products and is a deterrent to competition from vendors that might otherwise certify their products. This situation is playing out more and more frequently as clients realize the limitations placed on Health IT developers and the fact that many of these clients are smaller, rural hospitals that are already operating at or below margins.

We encourage CMS to consider add on payments for providers to offset the need for health IT technology. We also encourage ONC to provide guidance that clarifies that once a provider's contract is terminated, a Health IT developer can meet their obligations under the information blocking rules by providing a provider with all of their EHI, either to another vendor of Health IT or in another acceptable manner.

b. *What additional policies could ASTP/ONC and CMS implement to further discourage healthcare providers from engaging in information blocking practices?*

We believe there are three main issues related to provider engagement in information blocking: 1) lack of education, 2) lack of health IT capabilities or knowledge of how to enable relevant capabilities through their health IT and 3) lack of disincentives and enforcement of the limited disincentives that currently exist.

While the information blocking regulatory framework has been out for five years and compliance has been required for over four, there are still quite a few providers that are not aware of their obligations or have questions on what compliance entails.

Similarly, some providers are aware there are no disincentives for their provider type and/or there have not been any enforcement actions. As a result, some of these

providers do not feel an obligation to comply with the requirements as there is no teeth.

Additionally, there are a set of providers that operate largely on non-certified Health IT developers which means their Health IT developers have no obligations to comply with information blocking requirements. These providers may need to navigate compliance with information blocking obligations or their own or may not have access to the same tools that certified health IT developers offer as a result of the participation in the certification program.

c. *Are there specific categories of healthcare actors covered under the definition of information blocking in section 3022(a)(1) of the Public Health Service Act (PHSA) that lack information blocking disincentives?*

As noted in the previous section, the definition of health care providers is very broad, but only a select few within that definition have had any disincentives outlined by 'appropriate agencies.' Through rulemaking from the HHS, along with ASTP and the CMS, it has been made clear that these agencies consider themselves limited to creating disincentives via only a narrow list of pre-existing CMS programs under which the exchange of EHI is a key factor.

This presents an immediate issue that has led to only a select few provider types being subject to disincentives, and the impact is that a significant portion of stakeholders who directly affect the exchange of health data are not further incented to accelerate their standards-based exchange practices. More specifically, only those few healthcare provider types who have already had incentives to adopt, implement, and/or use certified health IT, or any health IT (such as through participation in CMS programs that measure interoperability), are affected by the recently finalized information blocking disincentive structure.

Included in the groups not currently being motivated by information blocking disincentives are several other critical stakeholder groups, such as labs, imaging centers, and pharmacies. CMS, ASTP/ONC, and HHS may need additionally regulatory authority or clarity to consider a broader opportunity for disincentives beyond their current interpretation.

Further, it must be noted that the current health IT model leaves out many healthcare providers from participating in the same robust exchange environment as other provider types, particularly those in behavioral health, long-term care, and post-acute

care settings. They have historically not been incentivized to adopt interoperable health IT systems, and they often face significant financial and technical challenges in upgrading their IT infrastructure.

This puts them at a disadvantage when it comes to meeting the interoperability requirements of the 21st Century Cures Act, including compliance with information blocking restrictions, and elevating their information exchange capabilities. We strongly encourage the consideration of targeted incentive programs for these provider types to accelerate progress in interoperability across all areas of care, as well as consideration to provide additional authority to CMS, or other appropriate agencies, to develop programs focused on the adoption, implementation, and use of health IT, certified or not.

19. *Regarding price transparency implementation:*

    a. *What are current shortcomings in content, format, delivery, and timeliness?*

    There are several shortcomings with the current hospital price transparency requirements.

    - **Manual Process:** The process of compiling data for hospital price transparency is highly manual and labor-intensive. Hospitals often have to extract data from various departments, systems, and sources, which are typically not centralized. This requires significant effort from hospital staff to gather, organize, and consolidate the necessary information.

    - **Planned vs. Executed Services:** There is often a disconnect between services that are planned, or that a patient may expect to be part of a bundle of services/procedure and what that patient actually needs. This could lead to inconsistencies between the information a patient sees as compared to the actual costs of the services.

    - **Changes in Delivery of Services:** Hospitals often face challenges in keeping up with the dynamic nature of healthcare service delivery. Changes in medical procedures, billing codes, or service packages can make it difficult to maintain accurate and up-to-date pricing information. This may result in outdated content or delays in updating the transparency data.

- **Lack of singular formatting - differences in contractual bundles/pricing structures**: Hospitals have different established prices for different services and bundles. Pricing can vary between payers, between plans, and even between hospitals in how they outline items in their chargemaster. This results in machine-readable files that can vary widely between hospitals making it difficult to determine compliance, completeness and accuracy with the CMS requirements and can result in belief that a hospital is out of compliance when they have met all the requirements CMS outlined.

- **Lack of Integrated Tools:** The current workflow may not have the necessary tools integrated into the correct stages of the process. This could hinder efficiency and timeliness. For example, if hospitals are using third-party companies to consolidate data, there might be a lack of seamless integration with the hospital's existing systems, causing delays and additional effort in data transfer and formatting.

To address these shortcomings, hospitals could consider investing in centralized data management systems specifically designed for healthcare pricing transparency. These systems could automate data extraction, ensure real-time updates, and provide a standardized format for delivering the required information to the public. Additionally, hospitals might benefit from developing internal processes that streamline data collection and validation, reducing the reliance on external parties and improving overall efficiency.

Similarly, CMS could consider adoption of a centralized hospital price transparency repository that would enable the normalization of pricing data and easier comparison across hospitals.

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

The workflows that would benefit the most from functional price transparency relate to the use of Patient Portal and Front Office Scheduling (Reg/Sched) products. Patients increasingly want to understand their financial responsibility and expected costs before scheduling a medical service.

By implementing functional price transparency, patients could access estimated costs and understand their potential liability at the time of scheduling. This is crucial as it helps patients make informed decisions, especially regarding potential cancellation fees and insurance coverage adjustments.

Integrating contract information and expected reimbursements into the front-office workflow will empower staff to provide patients with more accurate estimates during scheduling, whether it is done through the patient portal or directly with a staff member. This proactive approach to price transparency can enhance patient satisfaction and reduce potential confusion or disputes regarding medical costs.

Additionally, expectations to meet the good faith estimate requirements of the No Surprises Act are typically placed on the front office staff and met through use of the patient portal. Front office staff are working to deliver good faith estimate for the services delivered within their own office/facility, and in some cases working to obtain estimates from other providers to provider a more comprehensive estimate for the patient. Having pricing information in an easily accessible manner would ease the burden of compliance with the No Surprises Act.

c. *What improvements would be most valuable for patients, providers, or payers, including CMS?*

The improvements that would be most valuable for providers and patients, as outlined in the information provided, are centered around enhancing cost transparency, eligibility verification, and scheduling processes.

We believe centralization of data would be valuable to all stakeholders. If there were a repository of the pricing data published by providers and payers, normalization of the data could occur within the repository, easing burden on the parties. Comparisons of pricing would be much easier for anyone looking to do comparisons. Any consideration of ingestion of pricing data to provide references to patients/consumers or others, would benefit from a more centralized repository. Additionally, the centralized repository and ingestion of pricing, could assist in creation of a good faith estimate for patients, as required by the No Surprises Act, by enabling a provider or facility to obtain relevant pricing for most services.

One potential issue with the repository is not all providers are required to publish their pricing. Currently only hospitals, and the providers they employ, are required to publish pricing.

In addition, we outline the following considerations specific to the provider and patient stakeholder group -

For Providers: One of the key challenges providers face is the lack of automation in requesting and receiving price estimates for shared services, especially in complex procedures involving multiple providers. This will become a much larger issue as compliance with the good faith estimates of the No Surprises Act are enforced more broadly.

An automated system that facilitates this process would be highly beneficial to enable compliance. This system could centralize cost information from various providers involved in a service or procedure, ensuring that providers have a clear understanding of the financial implications before scheduling. Establishing a streamlined process for cost estimation would save time, reduce administrative burdens, and enable providers to offer more accurate and transparent pricing information to patients.

For Patients:

- **Portal for Eligibility and Contract Integration:** Developing a patient portal that integrates eligibility and contract information can greatly enhance service transparency. Patients could access this portal to view their eligibility status for different services, understand their contractual obligations, and make informed decisions about their healthcare choices.

- **Eligibility and Contract Transparency:** Patients often want to know their financial responsibilities upfront. Integrating eligibility and contract details into the patient portal provides clarity on coverage, co-pays, and any out-of-pocket expenses they may incur.

- **Propensity to Pay:** Assessing a patient's propensity to pay, or the likelihood of fulfilling their financial obligations, is another valuable feature. This information, which is already available through services like Experian, can help providers tailor payment plans or offer financial counseling to patients who may need assistance.

By implementing these improvements, patients can make more informed decisions about their healthcare, ensuring they understand their financial responsibilities and increasing the likelihood of successful payment outcomes. At the same time, providers can streamline their scheduling and financial processes, leading to better resource management and improved patient satisfaction.

d. What would further motivate solution development?

Hospital price transparency is a critical aspect of empowering patients and improving healthcare accessibility, but the lack of financial incentives has hindered the development of effective solutions. One of the primary challenges is that the data itself, although valuable to patients, does not inherently generate monetary value for solution providers.

To further motivate solution development related to hospital price transparency requirements, the following strategies could be considered – incentives and collaboration. CMS should begin by evaluating the price transparency requirements in existence, their shortcomings, and the intersection with the good faith estimate requirements of the No Surprises Act.

One of the most effective ways to create a market and motivate developers is through government intervention. CMS could seek to incentivize developers to ingest massive sets of pricing information from both payers and providers in order to determine more accurate pricing estimates and coverage information specific to the patient, which could then be made available to the patient at the appropriate time. CMS could also incentivize providers to make certain coverage and pricing information available to the patient at the time of care before a prescription is sent or a referral is made.

As noted in the response to the question immediately before this one, CMS could explore the possibility of creating a centralized repository of pricing information published by providers and payers. This one-stop-shop for digital health products would create some incentive in itself as these products must now work to ingest information from each individual hospital location and each payer/plan. That is a massive undertaking for the digital health product community to undertake, especially when there is not a clear market for the pricing information currently.

Collaboration between solution providers, hospitals, and industry associations could lead to the development of industry-wide standards and best practices for price transparency and good faith estimates required by the No Surprises Act. Some of the main challenges in providing accurate estimates prior to delivery of a service relate to understanding all of the facilities and providers involved, obtaining pricing estimates from all of them, and coordinating actual coverage and cost to the patient with the insurance payer. This collaboration might include data-sharing agreements, joint ventures, or the creation of industry-supported platforms. By working together,

hospitals and solution providers can create a more sustainable and mutually beneficial environment for price transparency solutions.

Section II.F – Value Based Care Organizations

Section 1 – Digital Health Adoption

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

   To encourage APMs such MSSP ACOs, other ACOs, or other APM to leverage digital health management and care navigation products, incentives must align with both financial and clinical outcomes. Opportunities include:

   Enhanced Shared-Savings Incentives Tied to Digital Engagement
   CMS should increase shared-savings percentages - or offer additional quality points - when accountable care organizations (ACOs) deploy patient-facing applications that have been reviewed and approved by CMS or that can verifiably close care gaps, prompt preventative care and care reminders, or otherwise assist in improving care quality.

   Prepaid Shared Savings and Advance Investment Payments Dedicated to Technology Enablement
   CMS introduced a prepaid shared savings option for existing ACOs in the MSSP ACO program in the 2025 PFS final rule. In the 2023 PFS final rule, CMS introduced Advanced Interest Payments (AIP) for new MSSP ACOs. Both of these programs enable ACOs, or those looking to form an ACO, the ability to invest in health technology and both were based on previous experience with similar payments through CMMI models.

   CMS should expand these concepts into other APMs as well. For example, in the new TEAM program, CMS considered a supplemental payment to certain safety-net hospitals but never finalized that ability. Safety-net hospitals historically operate at or below margin, making it difficult to invest in new health IT or digital health products that may impact care. Enabling these providers, and others, the ability to invest and drive down their costs and improve the health of their patients, is a great incentive, and similar to the

MSSP AIP and pre-paid shared savings concepts, CMS can seek to recoup its investments through shared savings recovery.

Activity-Based Payment Supplements for Verified Digital Interactions
CMS should establish risk-adjustment credits for validated digital encounters - such as remote physiologic-monitoring CPT events, chronic-care-management minutes, or secure-messaging consults - to ensure that technologically enabled care coordination is compensated in real time rather than retrospectively. This type of payment shift helps drive the healthcare ecosystem away from its encounter-based focus to more of an overall healthcare focus.

Streamlined Data-Exchange, enable Real-Time Reporting
Adoption of a common HL7 FHIR based reporting approach using HL7 FHIR Bulk Data Export - usable across CMS and NCQA programs - would enable continuous performance management while materially reducing reporting burden. Linking up the real-time reporting and provider incentives allows for real-time incentive feedback for hospitals and providers. Additionally, convergence in provider to ACO clinical exchange (QRDA to FHIR US Core) is key to driving data consistency and availability from HIT. We explore this in more detail in Section II.E Subsection 3 Question 9.

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?*

Key to the success of APMs is the ability to–achieve necessary goals in healthcare - better outcomes, lower costs, and reduced burden. All APMs involve some aspect of these concepts, therefore, evidence that AI, population health analytics, risk stratification, care coordination, usability, quality measurement, and patient engagement can help an APM achieve those goals and achieve shared savings, would drive many APMs to adopt those capabilities and embed them within their workflows.

In order to obtain the necessary evidence that these capabilities can achieve the noted goals, and to what extent each is able to impact a specific goal, will take time and investment from APMs. CMS could seek to incentivize APMs to adopt these capabilities and begin providing evidence of the impact of those capabilities as noted in our response to question 1 of this section above. Because these capabilities are an investment and cost the APM resources, there likely needs to be some incentive to initiate the adoption, or a disincentive/mandate to require it. Some APMs will adopt on their own, but that may not provide sufficient evidence necessary to move others or to drive future reform.

CMS should consider each of these themes and functionalities individually to determine priority in order of which should be incentivized or mandated first to last. Some of these are already embedded to some extent in the ability to provide the necessary services across a patient population that are required to impact cost, outcomes, and burden.

For most APMs, a comprehensive, longitudinal patient record should serve as the foundation, as it can enable accurate risk stratification, targeted care coordination, and population health insights that consider all clinical, financial, social, and environmental factors.

Going beyond the foundation of a longitudinal patient record, newer capabilities like AI placed on top of the longitudinal record can enable expanded data coverage and quality while reducing manual effort. Risk stratification – through this AI-enabled foundation – should drive core APM function to identify high-need patients based and ensure proactive and equitable care.

Similarly, care coordination is another foundational element of most APMs and must be supported through interoperable platforms that automate patient identification, track referrals, and deliver real-time care event alerts.

Additionally, APM related insights, should extend to patients directly via intuitive portals, notifications, and reminders that promote engagement to increase likelihood of achieving APM targets.

Finally, quality measurement should shift to automated, real-time tracking and submission capabilities, allowing providers to monitor performance and adjust quickly.

By beginning with a foundation of a longitudinal patient record and focus on care coordination, embedding these technologies — particularly AI, data infrastructure, and patient-centered tools — into APM design, models can drive more efficient, effective, and equitable value-based care.

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

VBC arrangements require broad, continuous, and secure access to patient data. Before any care planning patient notification, data extraction, or quality measures can be accessed, implemented, or utilized, it is essential for VBC organizations to have integrated patient data from a wide range of sources — clinical, claims, social determinants, pharmacy, and more, which is aggregated, normalized, and attributed.

This data can then be accessed or extracted to help VBC organizations view insights and promote optimized care delivery. With comprehensive data on a single platform, VBCs can eliminate the blind spots resulting from data silos, utilize intelligence for a more predictive and proactive approach to care plans and reporting, and enable clinical, care management, and financial teams to identify and address potential problems before they develop—reducing costs, increasing reimbursements, closing care gaps, and improving population health.

To that same point, we see HL7 FHIR Bulk Data Export as a key enabler of this data exchange but will require flexible mix of HIT (beyond traditional EHRs) to deliver modern scale and performance. We explore this in more detail in Section II.E, Subsection 3, Question 9. (repeated below for ease of reference)

> HL7 FHIR Bulk Data Export holds significant promise as a standardized approach for transferring large, multi-patient datasets across diverse healthcare scenarios while maintaining data fidelity. As digital quality measures (dQMs) take hold, and where needed inclusion of underlying source data, bulk FHIR allows for efficient data exchange by enabling comprehensive, population-level data retrieval in a single exchange, reducing repeated queries to source systems and supporting scalable, efficient data workflows.
>
> However, bulk data requests still place substantial demands on health IT infrastructure of EHRs that are primarily optimized for clinical documentation and real-time workflows—her high-volume data export. Requiring EHR systems to handle frequent or large-scale bulk data operations can degrade their performance and impact clinical availability.
>
> To mitigate this, flexibility is needed to allow the use of secondary data platforms for these purposes —such as health data intermediaries or population health tools—that are architected for large scale data exchange without compromising EHR operations.
>
> Additionally, even with widespread use of bulk FHIR, CMS would require a repeatable process for data retrieval across contributing health systems that can normalize across varying FHIR implementations without added burden on the provider's systems. A consistent approach for communicating patient attribution is also critical to enable correct data retrieval and inclusion for quality measure programs.

Lastly, privacy and security concerns should be considered in determining when to share the underlying source balancing the benefits and risks between distributed data analysis by the sources vs. centralizing the analytics.

At CMS' scale, unlocking the value of bulk FHIR for quality submission will require coordination with data producers (EHRs, Payers, etc.) and their software vendors to make data available. A strong technology company, like Oracle Health, will be a key relationship in collaborating with CMS and this broader community to push the necessary advances across the ecosystem (centrally or otherwise).

a. *Examples (not comprehensive) may include: care planning, patient event notification, data extraction/normalization, quality performance measurement, access to claims data, attribution and patient ID matching, remote device interoperability, or other patient empowerment tools.*

With a comprehensive longitudinal record supported on a single platform, unifying disparate data, VBC organizations can begin care planning, care delivery, and performance management.

To support care planning from a provider perspective, VBCs can deploy robust tools for clinicians at the point of care. For example, AI-generated summaries that provide insights into a patient's medical history such as smoking status, weight, diet, chronic conditions, etc. as well as intelligent notifiers for clinicians when patients are missing certain screenings or tests.

VBCs can also use remote patient monitoring to track patients and identify any risks, with tools like Bluetooth-connected scales that flag if Congestive Heart Failure (CHF) patients have a weight gain/loss of five pounds within a specified timeframe or glucometers that indicate when a diabetic patients glucose level is critical. With these insights, VBCs can appropriately engage with risk patients and reduce the impact of adverse events.

Health IT capabilities that empower patients to participate in their care can also dramatically support organizations in managing their value-based care patients. VBCs can engage their patients in their own preventative care with access to wellness programs, educational content, and electronic journals for health tracking. VBC organizations can also provide access to patients, such as availability of clinicians, nearby clinic and emergency department hours, and views that show comprehensive referrals and appointments across locations.

VBC organizations need robust analytics and reporting tools to effectively understand and manage their value-based care populations. Embedded outreach tools can further support patient engagement and measure tracking for VBC organizations.

b. *What other health IT capabilities have proven valuable to succeeding in value-based care arrangements?*

Beyond the health IT capabilities outlined above, VBC organizations can utilize artificial intelligence, integrated wellness registries, and contract performance analytics to further support their value-based care initiatives.

AI can be used to intelligently rank the highest-opportunity patients who would require the least amount of effort to close gaps in care and move the needles on overall VBC outcomes. Intelligence can also support wellness registries, with actionable insights to close gaps in care and optimize organizational performance.

With the overlap between contract performance and quality metric reporting, VBCs could benefit from comprehensive/robust analytics and reporting around contract performance. Contract performance analytics can provide insights from a financial and organizational standpoint, and help VBCs meet metrics, improve care, and generate revenue.

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

Successful value-based care programs must be grounded on the whole story of the individual based on a longitudinal record of care that extends beyond just clinical, payer, claims, and demographic data. Effective programs should also include:

- Behavioral health and socio-economic data: to manage patient's mental health and address barriers to equitable care access and costs.

- Geospatial data: to present location proximity of care services and provider networks, as well as exposure to environmental factors.

- Patient generated health data is also equally valuable as it encompasses additional data beyond the four walls of care, including but not limited to, self-reported outcomes,

alternative therapies, remote monitoring devices, and digital app integration. This data can surface proactive insights and guide patients in care management actions.

- Risk scores and stratification data: to enhance predictive analytics and prioritize patient care opportunities.

Section 2 – Compliance and Certification

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

The ONC Health IT Certification Program supports value-based care delivery by ensuring that healthcare technologies meet requirements for data-based quality measurements, interoperability, and patient engagement. These requirements and standards set accountable care models to ensure delivery consistency.

Major functionality requirements in the ONC Health IT Certification Program related to:

- **Electronic Quality Measures (eCQMs) -** eCQMs simplify and modernize quality performance reporting in a way that is directly tied to reimbursement and eliminates the need for retrospective reporting. Taking a more proactive approach to identifying patients who have care gaps or prioritizing patients who would be a good candidate for care management programs can reduce future care costs while incentivizing providers who are achieving the highest outcomes.

- **Interoperability -** Interoperability requirements allow healthcare organizations, payers, patients, and third parties to easily embed and share healthcare data. These data exchange requirements ensure that patient data is not siloed.

- **Patient-Focused Engagement Tools -** Certification standards support a patient's ability to be more self-reliant and proactive in their care by seamlessly communicating with their care team, sharing medical records, and contributing to a longitudinal care plan. Pushing out AI-driven clinical decision support to patients can alert them of short- and long-term risks such as readmission potential or chronic disease development. "Next best actions" can not only reduce the overhead burden of care management for providers but also allow a patient to take steps to reduce their own risk and prevent condition exacerbation. Proactive risk reduction can reduce costs for healthcare organizations, providers, payers, and patients.

6. *What specific health information technology capabilities that could benefit APMs are not currently addressed by existing certification criteria and standards that should be included under the ONC Health IT Certification Program?*

   The capabilities not currently included in the Health IT Certification Program that could benefit APMs are going to be dependent on the specific APM and its focal areas/goals. This is something we would expect CMS, CMMI, and ASTP/ONC to collaborate on to consider adoption of new VBC specific criteria as part of the program certification to satisfy APM-specific requirements for participation in addition to having a Base EHR certified product.

   We would expect that analytics-focused requirements may be an area of interest to support the ability of APM participants to track certain information and details for their beneficiaries, or to produce various quality reports in a standardized manner.

7. *How can technology requirements for APMs, established through CEHRT or other pathways, reduce complexity while preserving necessary flexibility?*

   While APMs balance cost, quality reporting, patient engagement, and care coordination, CEHRT and other interoperability pathways using certified HIT based on the applicable certification criteria can reduce administrative burdens by standardizing processes. This eliminates the need for custom reporting workflows that contribute to overhead costs.

   Certified HIT leverages standards like HL7 FHIR and other APIs to connect third-party applications into provider, payer, and patient workflows. This lets organizations easily adapt to new technologies and tailor them to a specific patient population, community need, or provider workflow.

8. *How can other HHS policies supplement CEHRT requirements to better optimize the use of digital health products in APMs? As an example, requirements under the Conditions of Participation for hospitals (42 CFR 482.24(d)) require hospitals to transmit electronic patient event notifications to community providers. What barriers are in place preventing APM participants from receiving the same notifications?*

   We are not aware of any federal barriers that would prevent APM participants from receiving ADT notifications. Many participants in APMs should be able to receive these ADT notifications upon request. The notifications would typically not go to the APM entity currently, but to the provider participants, which would then need to share the information if they so choose.

Some states have enacted laws expanding on the CMS ADT requirements as well, and we are not aware of any states that have attempted to restrict access to ADT data. Similarly, a few states have enacted laws restricting access to certain health information across state lines or in certain situations. In those cases, there may be an impact to the ability to share certain ADT notifications related to care outlined under those state requirements (such as abortion care).

9. *What technology requirements should be different for APM organizations when comparing to non-APM organizations (for example, quality reporting, and interoperability)?*

APM organizations rely on value-based care methods of delivery rather than fee-for-service models. Since the level of reimbursement is tied to quality reporting in this care delivery model, as opposed to non-APM/fee-for-service models, APMs have a greater incentive to meet and exceed measure performance. Health IT can support measure improvement and higher– reimbursement in three categories:

- **Analytics -** APMs need to capture clinical quality measures in their documentation, track performance of each measure in a dashboard, report measures to CMS. The MSSP ACO and APM Performance Pathway (APP) under MIPS are currently shifting to an eCQM model. Most APMs are unique in that their participants cross organizational lines and consist of different entities with different EHRs.

  Data ingestion across entities allows APM organizations to collect data from disparate sources and use that data to prove care gap closures have been completed. Dashboarding allows APMs to easily track measure completion MoM and YoY, and it allows for easy updates when new measurements are incorporated into value-based programs. Finally, quality measure data can be easily shared with CMS, accrediting agencies, and payers.

- **Population Management -** By ingesting, normalizing and standardizing data from disparate sources, technology provides insights that would otherwise remain hidden. For example, a patient with an emergency visit for a myocardial infarction would be difficult to track for the patient's primary care provider outside of the care network.

  Technology can provide alerts (like ADT notifications) and enable the primary care provider or APM to bring key diagnoses, lab results, procedures, and medications into a unified data platform and provide visibility for their primary care doctor. Next, the platform can use this data to recommend the patient for a heart healthy registry and suggest measures that will aid the patient in condition recovery and maintenance or improvement. The primary care provider can receive and act on these insights directly at the point of care through their natural electronic documentation workflow.

- **Care Coordination** - Many APMs struggle to get care coordination programs in place due to staffing shortages. Care coordination technologies can use a patient's longitudinal record to automatically identify patients that would be a good candidate for a care management program. It can prioritize patients based upon the greatest risk and benefit, and it can assign the patient to a care manager based upon items such as their specialty, location, languages spoken. AI tools can propose automated goals, interventions, and "next best actions" for the care manager to take based upon documentation in their natural workflow. Automated billing based upon time spent on each case can also help APMs to justify and expand their care management programs.

10. *In the Calendar Year (CY) 2024 Physician Fee Schedule final rule (88 FR 79413), CMS established that CEHRT requirements for Advanced APMs beyond those in the "Base EHR" definition should be flexible based on what is applicable to the APM that year based on the area of clinical practice. What certification criteria should CMS identify under this flexibility for specific Advanced APMs, or for Advanced APMs in general? Are there specific flexibilities or alternatives to consider for smaller or resource-constrained (such as rural) providers in meeting CEHRT requirements without compromising quality of care or availability of performance data?*

    The specific certification criteria and corresponding functional capabilities outside of the Base EHR definition from ASTP/ONC that will be of benefit for APMs will depend to a large extent on the specific goals and purpose of each individual APM. For example, an APM that is geared towards social determinants of health and care delivery to at risk populations could theoretically benefit from requiring health IT certified to the Psychological, Social, and Behavioral Data criterion at 170.315(a)(15). But that criterion is likely irrelevant for other APMs.

    The priority should be for individual APMs to consider what software capabilities are important to achieving their goals for the model and then (1) work with ASTP/ONC to consider existing criteria that align (or potentially pursue adoption of new criteria where relevant) and (2) provide absolute clarity to the industry and participants about the specific software requirements for participation in the model.

    The former Primary Care Plus program is an example of this. Initially the Primary Care Plus program was going to require support for the 170.315(a)(15) criterion and the Care Plan criterion at 170.315(b)(9), however these requirements were removed before the program officially began. These certification criteria were outside of the Base EHR definition from ASTP/ONC and CEHRT definition from CMS. We believe the criteria should remain outside

the definitions of Base EHR and CEHRT and be addressed as modular criteria that for specific programs can be bundled to support those programs using the appropriate HIT, including but not limited to EHRs.

It is also worth noting that the difference between the Base EHR definition and the CEHRT definition are relatively minor – only a handful of criteria. Maintaining the Base EHR as a "floor" for APM participation is sensible and should not be a major issue even for rural healthcare providers since it is a baseline for most EHRs in the market. But APMs need to be intentional about adopting additional requirements and criteria to understand the burden it may pose weighed against the benefits on a case-by-case basis.

Section 3 – Technical Standards

11. *What specific interoperability challenges have you encountered in implementing value-based care programs?*

Primary challenges with clinical data continue to be the result of fragmented systems and their inconsistent adoption of exchange standards (e.g., HL7 FHIR Bulk Data Export) that enable seamless data exchange for population scale data and outcomes. This frequently leads to continued dependence on document and file-based data exchange, which add data quality and latency challenges that impact the timely delivery of accurate insights for patient and financial outcomes in value-based care models.

Additionally, barriers remain in facilitating the frictionless exchange of data between payers and providers, limiting the real-time access to claims and utilization data - even with APIs like BCDA. This includes contract details themselves, which limits vendor's ability to provide advanced management and modeling recommendations for operating VBC arrangements.

An accelerated and expanded industry focus on enhancing bulk/population-level data exchange, including identifying appropriate use of HIT beyond EHRs considering performance, is critical to enabling the data exchange needs of VBC arrangements and network-wide quality programs more broadly.

12. *What technology standardization would preserve program-specific flexibility while promoting innovation in APM technology implementation?*

To preserve program-specific flexibility while promoting innovation in APM technology, it is crucial to establish common data modeling standards (e.g., HL7 FHIR) as well as rule/algorithm definition and execution standards (e.g., CQL) to allow programs to focus on

their core mission instead of data management and infrastructure. Ideally, these standards must promote extensibility to enable exploration of and ease of innovation contribution back to the standards.

Where possible, it is important to standardize expectations of the data exchange network (protocols, formats, real time data feeds, etc.) to ensure consistent normalization and promote reproducibility across implementations.

13. *What improvements to existing criteria and standards would better support value-based care capabilities while reducing provider burden?*

First, CMS should continue the efforts of the first Trump administration around Meaningful Measures, which reduced the number of measures and attempted to only present measure that could be evaluated and submitted passively, so that providers were not expected to manually collect and submit measures. During the first Trump administration the only measures were those that were claims based. In the advent of AI, it is possible to increase the number of measures and allow AI to collect data from EHRs without introducing provider burdens.

To better support value-based care and reduce provider burden, criteria and standards should prioritize the adoption of dQMs, a portable, standardized algorithm language, and automated, in-workflow reporting capabilities.

Unlike traditional quality measures, dQMs are designed for automation, interoperability, and the use of diverse data sources - including EHR, claims, and social determinants. By using a standardized, portable algorithm format (e.g., based on open standards like CQL and FHIR), measure logic can be defined once and executed consistently across different systems and care settings. This reduces the need for implementations, ensures alignment with evolving care models, and supports faster measure updates. We are exploring this topic more deeply with CMS in the concurrent IPPS RFI response.

dQMs enabled embedding directly into clinical workflows enables real-time, automated reporting from the point of care. This eliminates the need for retrospective chart abstraction and manual data entry, while also delivering timely feedback to clinicians. As a result, providers can focus more on delivering care, while the system handles performance tracking and reporting in the background.

14. *How could implementing digital identity credentials improve value-based care delivery and outcomes?*

Federated digital identity credentials sharpen data integrity, accelerate care coordination, and directly boost the cost-and-quality outcomes that define value-based care initiatives. Unifying patient credentials across disparate EHR systems, pharmacies, health plans, and other data sources, it solves the mismatch issue that can often skew quality scores and risk adjustments.

A single-trusted login allows patients to schedule care visits, share data, and provide patient generated results seamlessly, while providers and clinical systems receive accurate data in real-time. In addition, payers will benefit from cleaner data and lower fraud risk, which allows for sharper risk stratification and quicker shared savings calculations, reducing administrative overhead for value-based care program administration.

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 nationwide provider directory of HL7 FHIR endpoints would greatly simplify the *automated* curation of truly longitudinal patient data by allowing dynamic discovery and secure retrieval of usable patient data. Such a directory would require designation of supported resources, retrieval methods (e.g., HL7 FHIR Bulk Data Export), source/provenance aliases, associated organization hierarchy, and even metadata about the patient population backed by that API (benefit coverage mix, geolocations, demographics) to optimize discovery.

Today, this lack of discoverability leads to delays in contribution via HL7 FHIR and encourages continued dependence on legacy document or bespoke file-based exchange methods. A national directory would also further encourage vendor-to-vendor cooperation (discouraging walled vendor gardens) for the benefit of all providers, payers, and patients.

We do note that a robust national healthcare directory is not limited to capturing HL7 FHIR endpoints, but endpoints and addresses that are used for recognized standards-based APIs such as IHE Document Exchange APIs and DirectTrust Direct Secure Messaging APIs.