DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

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CODE360

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To Whom It May Concern,

On behalf of Code360 Inc., I am pleased to submit our response to the Request for Information focused on advancing a comprehensive Health Technology Ecosystem. As a mission-driven, SBA-certified 8(a) and HUBZone digital services firm, Code360 is proud to support federal healthcare initiatives with expertise in data interoperability, health IT modernization, and emerging technologies such as AI and machine learning.

We view this RFI as a strategic step toward building a unified, standards-based, and patient-centered digital infrastructure. Our team brings real-world experience delivering secure, cloud-native solutions aligned with federal frameworks, including FHIR/USCDI standards, Zero Trust architecture, and health equity goals. Our work with CMS, NIH, and CDC has positioned us to offer valuable insights into scalable, modular health data systems that empower both providers and patients.

In our response, we outline actionable recommendations around:

- Seamless data exchange through open APIs and FHIR-enabled services
- Responsible AI/ML use for clinical insights and population health
- Interoperability accelerators that reduce burden and enhance care coordination
- Secure, privacy-centric architectures to protect sensitive health data
- Governance models that foster innovation, equity, and trust

Code360 welcomes the opportunity to contribute to this critical dialogue. We look forward to partnering with you in designing an ecosystem that advances health outcomes, reduces disparities, and sets a foundation for long-term digital transformation across federal health programs.

Sincerely,

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1. Patient Needs

We all need a Knowledge Connected Healthcare Eco System

"The Collaboration Gap: Inefficiency in a Disconnected Healthcare System"

Despite the wealth of talent, data, and technologies in our country, a critical gap remains: **success stories are not shared or connected across the industry.** Providers continue to treat patients based on isolated experience and clinical playbooks—missing opportunities to learn from what has already "efficiently/innovatively" worked elsewhere.

Consider this: a patient suffered from blurred vision due to eye hemorrhage for over a year under one provider's treatment plan. Yet, when seen by a different research-driven specialist, the issue was resolved in just **20 minutes**.

The treatment existed. The data existed. The talent exited. But the connection did not.

Why aren't these breakthroughs—these life-changing success stories—collaborated and scaled across the ecosystem?

Imagine a national model where proven, high-impact treatment approaches are captured, validated, and shared. A system where patients and providers can access evidence-based paths to faster, higher-quality recovery. This isn't just a public health imperative—it's a business opportunity. Patients would gladly invest in proven treatments that lead to quicker, better outcomes.

It's time we close the gap—not just for innovation's sake, but for the millions whose health and lives depend on it.

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

Apps like MyChart, Wellthy, Papa, Rippl, SilverCloud, CarePredict, ianacare, maven clinic, Google Fit, Medisafe, Careclinic, Apple Health, Kaia Health, PeerWell, Japser Health,Health view, MyFitnessPal, Heartify, Welltory, FollowMyHealth, MyHealtheVet

Actions to be taken include;
An individual should identify their health needs and determine what tool will work best for them. Log into the apps, read summary notes and instructions from healthcare providers, add any loved ones into the apps, track medications, medications timing and any side effects, log in changes like pain levels, track sleep, mood, mobility and vitals, monitor activities like prolonged sitting

or sleeping and set alerts. Use the apps for secure messaging to communicate with healthcare professionals. Use the apps for virtual visits or appointments.
Users who trust apps have personalized the features, enabled real-time monitoring and can have direct contact with healthcare providers and can benefit from improved patient care.
With technology, an individual should go for apps or platforms that are user friendly, are well known or used in the healthcare field and compatible with various devices.
An individual should check the app's data privacy policy and understand how health data is collected, stored, and shared.
Review the cost of the app, many apps are free, and the user has an option of subscribing to premium features.

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?
Reminders and Alerts:

- For taking medications
- For annual check ups
- Proactive alerts based on history of events. For example, track the current mood, weight and blood pressure changes, and warn for any possible health concern
- Track and alert mood, weight

Create and manage a holistic health profile that is easily accessible.
Receive real-time alerts from the digital health application in the event of a potential health crisis or when predictive analytics detect abnormal vital signs. The system should proactively notify the user, and the caregiver, and recommend timely medical intervention or a visit to a healthcare facility, enhancing early detection and prevention of acute health events.
Track, remind and alert health progress on digital health tools. (Track medications, vitals, appointments, healthy lifestyle habits, life coach and providers involved in the patient healthcare).

Proactive alerts based on historical events—for example, continuous monitoring trends in mood, weight, and blood pressure to provide early warnings of potential health concerns.
Location-based alerts for environmental and health risks, including pollution, pollen levels, and disease outbreaks specific to the area.

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.
If getting care from large healthcare settings, for example hospitals or assisted care settings. The personal assistants are the ones who schedule the appointments and then communicate with the individual. Some large healthcare settings and Assisted living use apps like MyChart, and most patient services are uploaded in MyChart. Care givers or personal assistants have access to

MyChart, and through that you can access healthcare information.
The assistant can help the individual track vital signs and biometrics from smart devices, like smart watches.

Use software to track medications, when to administer medication as per the dose required, and when to refill the prescriptions.

Personal assistants can track reminders and follow-ups for preventive care like Immunizations.

The apps can be used to create diet, fitness and lifestyle support and be shared among the care support team.

The apps can also be used to track in network providers and estimate the cost of care.
Some apps can be used for emergency alerts; the apps can detect crashes in accidents and call emergency personnel and provide a digital health passport if the user has updated information. Smaller or private healthcare settings, like group homes still use traditional methods like having patient information on files, many homecare givers or group homes have not ventured into technology. The nurses or care coordinators help with scheduling for the appointments; they call the doctor's office and schedule the appointment.

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

a. If so, what are some examples of benefits it has provided?
MyChart can be accessed through mobile devices, making health management easy if an individual or loved one knows how to use the devices. Making it easy to access health information such as diagnoses, lab results, medications, summary of visits, immunizations, and care notes.

MyChart has made scheduling appointments easier, and an individual can get appointment reminders, access to test results, full access to medical records, get price estimates for medical services and procedures.

Prescription refills can also be done through MyChart and sent directly to the individual's address.

If an individual has some questions or what to communicate with the provider or the care team, this can also be done using MyChart through secure messaging.

Loved ones can easily access MyChart if the Individual gives them the credentials to access it and manage care. In cases where a care giver is needed the care giver can have access to manage the health care being given.

MyChart states that it is HIPAA compliant and patient data is secure and encrypted and to enhance that they have multi-factor authentication methods.

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?

If an individual had chronic illness or multiple medical conditions, it would be beneficial to have one portal or system to provide continuous access to health management.

One portal would make it easy for coordinated care across different providers. Referrals and records of care from different providers can be accessed in one place. Tests and procedures don't have to be duplicated if done within a certain timeframe.

One portal encourages communication between different healthcare providers involved with the individual to provide the best care.

One portal in emergencies will enable healthcare providers to have access to individual or loved ones' medical history, medications, current and past treatments. It will save time in the emergency room and reduce medical errors.

One portal gives an individual or a loved one the opportunity to track health metrics like blood pressure, blood sugar, thyroid levels, cholesterol levels and weight. Do follow-ups-through reminders for routine tests and share results with the care team.
Healthcare providers have access to the medication that an individual is using, and history can be shared between different pharmacies and doctors to check medication interactions and any interventions.

One portal is a good tool to use for procedures, especially for surgery and post-surgery follow ups. It can also be used for post-hospital care. Caregivers can monitor progress, and patients can report any changes or ask questions through the portal.

Post -covid many health organizations are encouraging Telehealth consultations. Providers can preview health records prior to virtual consultation, this saves time of travel, wait time for appointments, cut on costs for transportation for patients that need transport coordinated and leads to better patient care.

Updated one portal keeps all patient records current and prevents potential medical errors.

c. Were there particular datatypes, such as x-rays or specific test results, that were unavailable?

At times the portals are not updated. A patient can miss one or two results that do not reflect on the health record. It takes a very keen individual who tracks their health records closely to identify that a test or result is missing. This can happen when health records are shared between multiple providers.

X-rays must be sent in a different format (DICOM) to the provider. The patient cannot share directly what they can access or its not in the format required for sharing . The individual or personal assistant must submit patient records request for the images, and for the request to be sent directly to the different provider or if being referred to a specialty clinic.

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)?

Health systems lack agreements in place to push imaging data across different organizations. DICOM images also require PACS integration, which is not available in some organizations. If a provider uses a different EHR or does not participate in a HIE, medical records like X-Rays may not be shared in the patient's centralized portal. Patients will also have to consent for the providers to access the information.

Many individuals are overly concerned about protecting their privacy and health data. Campaign programs on data usage, security measures, and the benefits of responsible information sharing are much needed.

Cultural and religious beliefs – some individuals do not trust technology and may be hesitant in using modern technology in their healthcare management.

For individuals who are not tech savvy, it would be difficult for them to navigate the portal. Some healthcare professionals have expressed how challenging it can be to use some of the EHRs, and this can lead to health record data not entered correctly leading to care management misinformation.

Portals can at times have downtime or technical issues, this can lead to slow delivery of healthcare data and can impact critical decisions especially during emergencies.

An individual can need further interpretation of test results and when they are reviewing results by themselves it can be overwhelming and cause avoidable stressful situations.

Personal assistants or caregivers need to be tech savvy to navigate portals to interpret healthcare information and they might not have adequate training.

Healthcare settings use different Electronic Health Record (EHR) platforms, these platforms can have challenges communicating with each other. The EHRs are configured and managed differently, and this can cause fragmentation of healthcare data leading to an individual getting confused or getting anxiety based on the information accessed.

In the past, big companies have been hacked and asked for ransoms. Healthcare platforms are not immune to such threats. Hackers can target EHRs or Healthcare platforms causing panic and losing public trust.

A general concern about unauthorized access to healthcare data makes individuals and loved ones question the technology systems instead of taking advantage of the benefits.

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

Beneficiaries who are in senior living care sign service agreements and the health management is handled by the healthcare personnel. Most of the beneficiaries prefer the caregivers to handle tech care management. They can ask for notes, charting records that are printed and issued to them, they have access to the doctors through telephones or coordinated telehealth visit. Caseworkers are the ones who manage the records. Some of the EHRs used are like RTask, Eldermark among others and have mobile apps. Medicare billing is done directly from the apps. Individual beneficiaries have access to apps through the integrated EHR system of the healthcare provider that they are using or through a third party. For example, to check insurance coverage, they can download the app the insurance company is using to provide Medicare eligible services or create an online account. Some EHRs like RTasks are flexible and can be accessed through different devices at anytime and anywhere.

PC-4. What features are missing from apps you use or that you are aware of today?
Data integration from all healthcare providers/settings into one place. Proactive alerts based on historical events—for example, continuous monitoring trends in mood, weight, and blood pressure to provide early warnings of potential health concerns.

Access to complete health history regardless of where you are in the country.
The Apps available are good for recording data but do not provide more information on mitigation factors on any anomalies detected.

The Apps should have offline access.

Customization of the Apps to meet the individual needs, for example multi-lingual, and send appropriate cultural and religious information.

Provide realistic information based on the specific individual needs, can use integrated data to give the patient cost estimates based on the insurance plan or self-pay.

Onboarding of the Apps for user- friendliness especially if the user is not tech savvy. It should be easy to ask questions and get quick responses if the user is having difficulty navigating the app.

The Apps should have short structured plain language explanations of data privacy and security. Individuals and caregivers at times do not have the patience to read the lengthy disclaimer closures and acknowledgement.

a. What apps should exist but do not yet?
Health metrics monitoring apps should integrate with the mobile apps, for example, Blood sugar monitoring patch should integrate with mobile app directly, and the individual does not have to manually do the prick test and enter the results. It should read the levels and record the sugar readings automatically and send it to the providers or care team.

Why do you believe they do not exist yet? A bi-annual glucose monitoring option exists through implantable Continuous Glucose Monitors (CGMs), but there is a growing demand for even more advanced and user-friendly solutions. A smart patch that continuously tracks glucose levels and syncs with mobile apps could offer a non-invasive, real-time alternative. This technology

would improve diabetes management by delivering continuous insights while eliminating the need for frequent finger pricks, lab visits, or invasive procedures.

b. What set of workflows do you believe CMS is uniquely positioned to offer?
CMS is positioned to offer streamlined reporting analytics on healthcare data. Engage actively by supporting public health and surveillance from a health equity lens.

Making healthcare affordable to all by regulating payments that individuals can make.
CMS has the capacity to work with different States, interact with the private sector and healthcare professionals. Acting as a bridge among these entities to make healthcare accessible and affordable.

Research workflows - Proactively engage in research, funding research to be able to make informed policy decisions based on the data collected.

CMS is already driving national standards through Blue Button 2.0 workflow, which has allowed beneficiaries to interact with third-party apps sharing Medicare data. And standardizing data exchange rules between payers and providers.

CMS can determine the quality-of-care individuals can get by having adequate funding for Medicare payments to hospitals and health systems.

CMS can expand healthcare access for all encompassing all medical services.

CMS can control healthcare services through regulations and negotiations.

CMS can consolidate all its services in one place. Payers and providers can have one coordinated place to interact with instead of multiple third parties.

CMS can drive health equity by advocating the same standard of service across all hospitals. For example, an individual does not have to go to another State to get healthcare services because it is cheaper or affordable there.

PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?
Patients in facilities do not utilize the apps frequently but the ones who have admitted in the facilities use digital health products for care management. When they get to the facilities, the facility takes up care-coordination and management because some individuals are no longer independent or prefer the care givers to manage everything. Care givers should get more training on how to use healthcare platforms to provide better care.

CMS can expand ACO incentives to reward providers for promoting patient use of digital health products and ensuring that data from these products is shared with CMS for centralization on MyMedicare.gov. CMS can offer rewards or discounts for those who engage with digital health platforms. They can partner with other programs that the individuals might benefit from and offer incentives through those programs too.

CMS can have a program that offers smart devices to individuals that do not access such devices.

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?

CMS may need to collect information on the digital tools and health products used by patients during the claims process and integrate this data into value-based care programs to assess effectiveness.

CMS should use a universal data standard that is easy to implement for digital performance on their programs. CMS can extend the use of open standards like FHIR for data exchange. CMS should actively review and evaluate digital health products and tools that are efficient and accessible to all.

CMS should provide technical assistance and education to FFS providers, MA plans on the benefits of digital health products and how to integrate with mymedicare.gov and promote them to beneficiaries.

CMS should proactively promote MyMedicare.gov and its integrated apps to beneficiaries, highlighting the benefits and how healthcare management can be simplified.

CMS should engage in public health and surveillance for digital tools and what works best in the interest of the public. CMS should actively participate in public engagement forums. Engage with healthcare professionals, patients and partners to understand the effectiveness and concerns of digital health products and ensure that surveillance efforts are patient-centered and responsive to real patient expectations.

CMS should expand the functionality of Blue Button 2.0 to integrate with FHIR-based APIS, this will facilitate the flow of data from digital health products into a centralized, interoperable system for surveillance. CMS will be able to track the utilization of digital health products across different populations, identify where the products are effective and where disparities exist.

CMS should proactively strengthen its data security and privacy policies to safeguard sensitive health data within digital health tools, effectively preventing breaches and securing public trust.

CMS should offer incentives or bonus payments to healthcare professionals or vendors that utilize digital health products. ACOs can reward providers for effective use MyMedicare.gov-integrated apps to remotely monitor patients with chronic conditions to reduce emergency or hospital visits.

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)?

Make technology user-friendly. Systems should easily integrate with healthcare platforms, third-party apps to allow seamless data sharing across providers.

Design accessible systems. This will ensure that all users can easily use systems despite the differences in demographics.

CMS should review licensing requirements for healthcare professionals. This will allow the use of digital services across different regions for better healthcare.

Engage in Digital Outreach campaigns to raise public awareness on the importance of digital health tools and how they improve healthcare management.

b. What changes would enable timely access to high quality CMS and provider generated data on patients?
CMS needs to extend the use of interoperability/ FHIR standards for all its partners. This can enable sharing seamless data across systems.

CMS should have one portal, the partners will have all data centralized and can link with partners generated data. For example, link with different EHRs.

CMS should simplify regulations on Providers to share data. Providers should have access to grants, or payment incentives, to coordinate data delivery to CMS. Providers can use these resources to scale up the EHRs to ensure automated data flow to CMS systems eliminating the need for manual data extraction and submission by providers/providers personnel.

CMS should foster interoperability among, patient portals, MyMedicare.gov and health apps, for example fitness apps to promote health quality, better patient outcomes and encouraging caregivers/families to better support their loved one's health.

Patient engagement, build public trust and promote use of digital health tools. The initiative can empower patients to access and share their healthcare data. Patients can have real time access to care management documents and can share with Blue Button via third party apps.
CMS should enhance its data governance, security and trust frameworks. CMS programs should be explicitly included in data frameworks like TEFCA.

PC-6. What features are most important to make digital health products accessible and easy to use for Medicare beneficiaries and caregivers, particularly those with limited prior experience using digital tools and services?
Strengthen data privacy and health data protection to address beneficiaries' concerns. Campaign programs on data usage, security measures, and the benefits of responsible information sharing are much needed.

Voice biometrics can be used to securely identify providers, patients, or caregivers to access medical records.

Digital health products should use a standardized format for seamless data exchange between different systems for smooth transition of care (FHIR APIs).

Offering digital training programs and resources in different formats to cater for marginalized/underserved communities. Resource examples might include: online tutorials, videos, materials that can be distributed to community groups that support Medicare and Medicaid populations.Digital health products support remote health monitoring from integrated digital tools. For example, wearable devices can allow for detection of anomalies and quick interventions.

Digital health products can have voice enable features that simplify the use of the products. For example, patients with physical or technical limitations can activate voice commands to interact with the products.

Voice activated reminders and alerts. Voice assistants can remind the users to dispense medication, take medications and read the instructions or facilitate communication with caregivers.

Caregivers should have easy access to health information to help with tasks like appointments, coordinating care plans for better continuity of care and coordination.

Digital health products should provide quick and easy access to customer support through different ways, for example, phone, live support, voice chat.

User-friendly interface that is simple to use with customizable features, easy to the change font size, contrast colors and user can voice activated feedback on actions taken.

Voice features can assist in placing hands free emergency calls in crucial times, in emergency centers voice tools can offer hands-free access to services, for example accessing information from machines when providing care and avoiding contamination.

Providers can dictate clinical notes directly into EHR using voice tools making it easier for caregivers and patients to get care, and timely feedback. It helps providers with easy documentation, or to set reminders, schedule follow ups or order prescriptions. For example, integrate centralized EHR with tools like Dragon Ambient Express.

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

CMS already has programs that it can leverage to collect real-world data. For example, if can expand the Blue Button to integrate with additional third party apps. Collect data from Chronic care management. Integrate use of digital health products into existing quality programs and alternative payment models deployed by the Innovation Center.

CMS should have a centralized portal to collect data. This can be used as a registry for digital health tools. Patients, and caregivers, should be able to access the data via Mymedicare.gov to

easily have a complete picture of their medical information and be able to share that with their healthcare providers.

Collaborate with partners on transparent research on the efficiency of digital health tools. CMS should frequently update the websites, conduct surveys with providers, app developers and beneficiaries.

CMS could use a combination of Medicare claims data, patient satisfaction surveys, and analytics from app developers. Metrics could be integrated into Star Ratings or value-based care performance tracking.

2. Data Access and Integration

PC-8. In your experience, what health data is readily available and valuable to patients or their caregivers or both?
EHR data- patients can access digital records through patient portals, this allows the patient and caregivers to have access to immunizations, vitals, shared vitals, labs and tests, health history, journals to manage health and fitness, goals, electronic record sharing options with community providers who are part of care team and in the seam exchange system. Eg (Veterans Health Information Exchange (VHIE).

Patient data such as demographics, payment information and coverage, pharmacy (refill prescriptions, track delivery, medication lists), secure messaging, care givers information, information on treatment facilities, health calendar, order medical supplies, care summaries and notes,

Telehealth and remote monitoring. Devices can monitor chronic conditions remotely and send data to caregivers or providers.

Resources for Mental Health, Whole Health, Mobile Apps supported.

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)?
Test and results – some results can be hard to interpret for the patient because of the clinical language used. If the patient or care giver wants to download images, the format is Digital Imaging and Communications in Medicine (DICOM) and that is not accessible to the patient or care giver.

Medical records fragmentation across systems.

EHRs should be interoperable across all systems.

Access to certain medical records due to privacy and security, sensitivity of the information is governed by regulations and access granted can be very limited. For example, mental health records.

Limited access to some medical records limits app developers in developing personalized health care plans to deliver better healthcare treatment and management.

EHRs are different and cause interoperability issues, the app developers do not have access to the different EHRs, and some EHRs are very hesitant in sharing information on how the systems operate.

Appointment schedules are both beneficial to the patient and caregivers for planning purposes.

With some EHRs patients can schedules appointments but it is not integrated to the health calendar. Developers can integrate appointment data in the health calendar and apps to send auto reminders to enhance functionality.

Role based access restrictions can limit app developers' valuable insights for predicting patient care and optimizing treatment.

Claims data is owned by third parties, like payers and access is restricted. Patients and providers can have limited access and developers must seek patient or provider consent or work with the payers limiting the scope of their work.

Privacy and confidentiality laws make it difficult to share information like Pharmacy records, integrating the information into one system requires additional consent from the parties involved. EHRs use different standards and developers find it challenging to use different standardized formats to create centralized tools that integrate across all devices and platforms. Standardization and incentives are needed to overcome data silos and EHR incompatibility. It is challenging to employ an equity lens and collect social determinants of health indiscriminately. Patient social data is recorded inaccurately or rarely captured yet such data can help improve healthcare by addressing non-medical factors that can affect health. App developers can incorporate such information to personalize care plans.

Healthcare prices should be transparent to patients to make informed decisions on the cost of care and having different options and compare different healthcare providers. Pricing should not only be machine readable but also decipherable to a consumer. It should inform a healthcare consumer of what they will pay for an episode of care based on their insurance. Developers should have the correct information on pricing provided to them without hidden costs, to build tools for patients to use to estimate care and have financial transparency.
Medical devices should function as they are marketed, for example wearable devices should work in real time in monitoring chronic conditions, vitals and detect anomalies (e.g.,high blood pressure, increased heat rate, monitor heart attacks and strokes). Some devices malfunction and this can lead to fatalities. App developers and medical devices companies should be transparent on the life cycle or operability of the devices.

b. What are specific sources, other than claims and clinical data, that would be of the highest value, and why?
Social determinants of health and caregiver documentation would add value. Social determinants would give more insight into non-medical conditions that impact health. Caregiver

documentation will enhance the quality of care, caregiver responsibilities and time worked are also included in the documentation.

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?
Standardization is needed to overcome data silos and improve EHR incompatibility.

Opportunity to offer incentives to Tech vendors and partners to promote interoperability.

Exploring cloud-based platforms. Most companies and organizations are moving to the cloud for centralized storage and the cloud can store large data sets, simplifying integration from multiple digital tools.

Challenges
Data privacy and security concerns. Maintaining patient confidentiality is crucial when sharing data, this can impact data integration efforts and research.

FHIR has still not been well adopted in the health industry. Healthcare organizations still use other standards that result in data silos and affects EHRs combability.

Smaller health organizations or research facilities lack adequate funding and resources to invest in data infrastructure and technical expertise.

PC-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?
Data from ACO, QIO, value based and other community programs.

ACO partners and providers can use integrated apps to monitor and identify gaps in care coordination. This makes it easy to identify providers collaborating to provide care.
Real-time notifications to patients to be alerted on authorized services or any denial of service.

QIO can include hospital/provider reviews to alert patients and caregivers on the ratings of facilities.

Value based care can provide provider ratings for quality, high performing and cost-effective providers.

Community or social care data can help beneficiaries with providing more resources for health that are beyond the clinical settings. For example, transportation, services for domestic violence victims and survivors etc.

Medicare Advantage (MA) data covers extra benefits like dental, vision and transportation and can help patients to understand and utilize all services available.

Add Payers data to help patients compare providers, estimate out of pockets costs and make informed health care decisions.

a. What difficulties are there in accessing or utilizing these data sources today?
Delays, inconsistent data formatting, and lack of integration with state Medicaid or Advantage plans.

Medicare Advantage plan only has Part D information available in Medicare Apps, Part A and B are provided by the beneficiaries' plan.

b. What suggestions do you have to improve the Blue Button 2.0 API experience?
Adding lab results, referrals, treatment plans, social services data, pharmacy and behavioral health data would enhance usefulness.
Integration of all information into a centralized platform Medicare Part A, B, C and D should all the integrated.

c. Is there non-CMS data that should be included in the API? CMS can explore ways to capture social determinants of health.

PC-10. How is the Trusted Exchange Framework and Common Agreement™ (TEFCA™) currently helping to advance patient access to health information in the real world?
a. Please provide specific examples.
TEFCA has a standardized framework for health data exchange using the same EHR vendor.

Health Information networks (HINs) supported by TEFCA has a secure way to exchange health information among the networks enhancing trust among the participants.

Patients can have easy access to health data from multiple providers.

Healthcare settings under QHIN are coordinated to follow TEFCA common rules of data exchange under the Common Agreement. This strengthens the privacy and security of healthcare data.

b. What changes would you suggest?
It is not clear how TEFCA supports rural and underserved communities. HINs are all bundled with Qualified Health Information Networks (QHINs) and it is not clear how this will address health disparities.

c. What use-cases could have a significant impact if implemented through TEFCA?
Useful cases include:

Completed patient records at the point of care. Providers will have access to complete patient medical records without worrying if its in network or out of network facility.

Appointment coordination, patients get fast booking of appointments and get prompt care.

Automated referrals and data exchange enhance care, save time, and improved reporting

Patient centered model to promote patient engagement. Patients have control, easy access to health information and can make better informed decisions.

Patients can access health information through apps and easily share the information with a new provider, if the records are not available or in case of an incomplete record sent.

Promote exchange of data with Public Health Agencies, supporting a more robust public health infrastructure.

d. **What standards are you aware of that are currently working well to advance access and existing exchange purposes?**
HL7 FHIR and SMART on FHIR are working well; XCA and XDS could be expanded.

e. What standards are you aware of that are not currently in wide use, but could improve data access and integration? HL7 FHIR and SMART on FHIR are now being adopted but some health organizations still use outdated standards.

f. Are there redundant standards, protocols, or channels that should be consolidated?
HL7 v2 is not flexible as HL7 FHIR even though it has been the dominant standard.

Direct messaging and IHE profiles should be streamlined with FHIR security and messaging standards to reduce redundancy.

Claims data is exchanged through X12 or NCPDP that may not be able to integrate with other platforms. Having one standard like FHIR facilitates seamless exchange of data.

g. Are there adequate alternatives outside of TEFCA for achieving widespread patient access to their health information?
CommonWell and Carequality offer alternative frameworks.

PC-11. How are health information exchanges (HIEs) currently helping to advance patient access to health information in the real world?
HIEs provide essential health data. Care providers can coordinate care through HIEs.

Providers can get patient information from HIEs during emergencies to provide care with minimal errors.

HIEs allow patients to control data they want to share.

a. How valuable, available, and accurate do you find the data they share to be?
HIEs are digital and this reduces the risk of losing data.

If data is entered accurately, chances of manipulation are minimal because it is digitally stored, and access permissions should be in place to reduce medical errors.

b. What changes would you suggest? Standardized participation and funding could improve consistency.

c. Are there particular examples of high-performing HIE models that you believe should be propagated across markets? The Indiana HIE model demonstrates success.

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 should complement national networks and patient-facing applications by providing localized and real-time data.

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

a. Examples may include the following:

(1) Binding cost estimates for pre-defined periods.

Binding cost estimates and provider directories exist but are fragmented. This should consolidate to one standard.

(2) Viewing provider schedule availability.

In most cases Patients do not have access to provider's availability. They must coordinate with coordinators to schedule appointments. The provider calendar is managed with a coordinator, and they must call back to confirm appointments. Coordinators can create alerts to confirm appointments in real time.

(3) Using third-party apps for appointment management.

Caregivers and patients can schedule appointments through third-party app but at times it will take time to confirm the appointment or get a quick appointment. They end up following up with the provider's office to get timely appointments. Some apps can schedule an appointment for a couple of months out. Third-party apps need to have automatic calendar updates to schedule patient appointments promptly.

(4) Accessing patient-facing quality metrics. Providers compile data about patients and have the data in a centralized place to provide better care for patients and reduce competition among providers.

(5) Finding the right provider for specific healthcare needs. Update the providers registry with their specialties and reviews. Clearly indicate if they are in network or out of network for insurance purposes.

b. What use cases are possible today? Universal provider registry, transparent healthcare costs, enhanced communication and care coordination, leverage AI to help with healthcare tracking and management.

c. What would be possible in the near future? Seamless scheduling and unified provider quality dashboards should be near-term goals.

d. What would be very valuable but maybe very hard to achieve? Comprehensive, real-time pricing transparency linked to individual benefits remains as a challenge but critical goal.

3. Information Blocking and Digital Identity

PC-13. How can CMS encourage patients and caregivers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? Embedding complaint prompts in patient portals and EOB statements would raise awareness. It could encourage transparency and accountability.

What would be the impact? Over-reporting might strain system resources.

Would increasing reporting of complaints advance or negatively impact data exchange? If resources all complaints can be reviewed and action taken to improve data exchange. If allocated resources are inadequate or limited the complaints can strain system resources.

PC-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? Lack of awareness, complex registration, hesitation to share personal identifying information and digital literacy barriers.

b. What could be the benefits to patients/caregivers if digital identity credentials were more widely used? Simplified access, secure data exchange, and caregiver account linking.

c. What are the potential downsides? Privacy and security concerns. Lack of trust. Ransomware attacks have been on the rise targeting government entities, large corporations and organizations.

d. How would encouraging the use of CSPs improve access to health information? Educate Patients that they do not need to re-enter biographical information, it's all under one account it requires a single sign-in to access health information. Only authorized users can access patients records as the health identity management provides protection.

e. What role should CMS/payers, providers, and app developers have in driving adoption? Do outreach and educate the public on the importance of digital identity protection through CLEAR, Login.gov, ID.me etc.

f. How can CMS encourage patients to get digital identity credentials? CMS could integrate credential setup with Medicare enrollment, promote public education campaigns, and standardize identity systems across EHRs.

C. Providers

This section is intended for all stakeholders to provide input on questions as they relate to use cases and workflows that involve providers. While we certainly want providers to answer

questions in this section (and in other sections) from the provider point of view, we also invite all stakeholders to provide their viewpoints on the provider workflows as appropriate.

1. Digital Health Apps

PR-1. What can CMS and its partners do to encourage providers, including those in rural areas, to leverage approved (see description in PC-5) digital health products for their patients?

CMS can offer training, rewards or discounts for those who engage with digital health platforms.

They can partner with other programs that the individuals might benefit from and offer incentives through those programs too.

CMS can have a program that offers smart devices to hospitals that they can distribute to individuals that do not access such devices.

Offer better opportunities to personnel(better pays) who serve rural communities and improve technology in rural areas. Rural areas should have reliable telecommunication and internet services.

Offer digital literacy training to the rural communities.

a. What are the current obstacles?

Many individuals have significant concerns about the privacy and security of their health information. To address this, there is a growing need for awareness campaigns that educate the public on how their data is used, the policies in place to protect it, and the positive impact that responsible data sharing can have on their healthcare experience. Limited or insufficient investment in technology infrastructure.

Lack of specialized workforce in rural areas, like Tech specialists, Tech-vendors, providers, caregivers etc.

b. What information should providers share with patients when using digital products in the provision of their care? Providers should share the benefits of using digital products, explain to patients the different types of digital products and tools that they can use for their care and purpose in enhancing patient care.

Providers can have FAQs and learning materials that they can share with patients.

c. What responsibilities do providers have when recommending use of a digital product by a patient? Providers should provide information on how and what services they can provide care for through digital products.

Patients trust their providers more than anyone else, which means providers have a greater responsibility in promoting the digital products.

Educate their patients about the privacy and health data protections offered by digital products, while also highlighting the benefits these tools provide in improving care, enhancing access, and supporting better health outcomes.

Providers can organize community outreach activities to share more information on digital products.

PR-2. What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows, such as quality measurement reporting, clinical documentation, and billing tasks? How could these obstacles be mitigated?

Physicians concentrate on patient care and can suffer from burnout, especially if they must work on reports, documentation and billing tasks in addition to their practice.

Inadequate resources for health organizations. Limited budget for Tech specialists.

Different standards cause interoperability issues and data silos. Lack of enhanced and certified EHRs.

Introducing new systems and EHRs can disrupt patient care and be a burden. Physicians can resist change even if it is a better system.

Mitigations
Healthcare organizations should be well funded to deal with staffing issues and hire tech professionals.

Standardize data exchange, adopt open standards like FHIR.

Invite physicians to contribute to work-flow analysis and what would work best for them. This will allow easy integration into the existing workflows.

Provide training for healthcare staff on new applications and the interface that are being used. Carryout Implementation in stages.

PR-3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an HER 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:
a. Current challenges in accessing different data formats.
Different data formats can lead to data fragmentation leading to misinformed decisions in patient delaying care.

Inefficiency can lead to extra costs; staff need to review the different formats and reenter data

leading to errors.

b. Impact on patient care quality. Fragmented patients' data can lead to gaps in delivering patient care. Providers might have difficulties transitioning patient care as a result and lead to medical errors.

Patients might incur additional costs on repeat tests and procedures.

c. Technical barriers to full data accessibility. Outdated and immature standards, use of different EHRs, technical differences and problems with compatibility, fragmented data, privacy and security concerns, Lack of technical staff.

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

e. Priority level compared to other interoperability needs. The priority level of technology infrastructure should be high compared to other interoperability needs. Without a strong foundation of reliable infrastructure, data exchange efforts cannot function effectively. This directly impacts the accuracy, timeliness, and completeness of patient information ultimately affecting the quality and coordination of care.

PR-4. What changes or improvements to standards or policies might be needed for patients' third-party digital products to have access to administrative workflows, such as auto-populating intake forms, viewing provider information and schedules, and making and modifying an appointment?
Add changes to policy and procedures under acceptable use policy (AUP) and provide this upfront prior to accessing or utilizing administrative workflows.

Making and modifying appointments should be done online without consulting care coordinators.

Third party digital products should embrace the use of advanced security features such as biometrics, passkeys etc, to complement security.

2. Data Exchange

PR-5. Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:
FHIR APIs use OAuth2.0 is for security and authorized access.
FHIR RESTFul APIS calls (GET, POST, PUT, DELETE).

a. Patient Access API
Utilize Patient API for individual queries. Patients can schedule appointments, access health data.

Bulk queries are used for analytics reports.
OAuth2.0 is used for security and authorized access. The system must also comply with data privacy policies such as HIPAA.

b. Standardized API for Patient and Population Services – Patient focused on specific patient care. Individual queries are performed, patients can access health records, and this can be used for specific care coordination. Use OAuth 2.0 and must comply with data privacy policies.

Public Health organizations can use Population services for research and public health initiatives. Uses Bulk queries (FHIR Bulk Data Access, uses $export Operation). PII data must be removed from bulk data, the entities must comply with data privacy policies, such as HIPAA and CIPSEA.

c. Provider Directory API – Patients and providers can use the directory for referral or care searches. Insurance also utilizes the API to check for in-network and out of networks providers. Individual and bulk queries can be performed. Must comply with data privacy policies.

d. Provider Access API – Used to access patient data in real time and managing care across multiple providers through individual queries and must comply with data privacy policies.

e. Payer-to-Payer API – used by insurance companies, sharing plans information, and confirming patients' eligibility. Used bulk queries in cases where patient's coverage is being shared with multiple insurances.

f. Prior Authorization API – Bulky queries for requests of authorizations to provide patient care. Patients are being referred to specialty care or emergencies. Use multiple FHIR resources and must comply with data privacy policies.

g. Bulk FHIR – Do you support Group ID-based access filtering for population-specific queries? Bulk queries, used to retrieve survey data. Restrictions on the kind of data that can be shared, PII data and certain data sets cannot be retrieved.

h. SMART on FHIR – Do you support both EHR-launched and standalone app access? Yes
What does the process for application deployment entail? Third party apps can be launched independently or within the EHRs, the Apps need authorization to access data. The Apps need to be registered and deployed.

i. CDS Hooks (for clinical decision support integrations)- Individual queries, patient-specific information from the EHR to enhance healthcare management. Different EHRs perform differently and this affects interoperability.

PR-6. Is TEFCA currently helping to advance provider access to health information?
Provides a standardized framework and uses one EHR across multiple HINs under QHINs.

a. Please provide specific examples.

Provides one platform for providers to access and share patient data. Provides universal standard for data exchange among different providers.

b. What changes would you suggest?
TEFCA should expand to all areas including rural and underserved areas. Provide incentives and resources for participants. Make TEFCA accessible to all health organizations, large or small.

c. What other options are available outside of TEFCA?
HIEs, Private Health Networks, CommonWell and Carequality

d. Are there redundant standards, protocols or channels or both that could be consolidated? Consolidate HIEs, Private Health Networks, CommonWell and Carequality

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

Incentivize and establish minimum acceptable guidelines for EHR vendors to implement the required data-sharing capabilities.

Providing more information on TEFCA and training. Encouraging healthcare organizations to adopt FHIR. Incentives and providing more funding resources.

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

- Implement data quality framework inside EHR systems.
- Automate/guide clinical data entries.

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 would reduce the administrative burden, minimal data error because of consistency of data shared using one standard. Bulk FHIR can pose as privacy and security threat in case of a breach. It also needs a high level of technical expertise to implement.

b. In what ways can the interoperability and quality reporting responsibilities of providers be consolidated so investments can be dually purposed? Use one standard (FHIR), utilize cloud platforms to store data in one place, consolidate regulatory reporting requirements.

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? Data registries should use the same standard and automation. Eg, FHIR.

Establish clear guidelines for data provenance and data quality checks in registries.

Standardize quality measures across different CMS programs

Promote the use of cloud-based infrastructure to handle large volumes of data and simplify data analysis.

Enhance date privacy and security measures to protect sensitive patient data and ensuring compliance with privacy policies like HIPAA.

3. Digital Identity

PR-9. How might CMS encourage providers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins that need to be tracked for each provider relationship? Educate the highlights the current real-world use of digital credentials and their security advantages over traditional login methods.

Create awareness programs and do outreach and education on the benefit's digital identity credentials.

CMS can offer technical assistance and training to help providers implement digital identity credentials into their workflows.

Integrating the systems to support digital identity sign in and comply by privacy data regulations. CMS can provide clear guidelines for privacy and security of patient data using digital credentials by addressing privacy and security concerns.

CMS should introduce incentives for providers implement and adopt digital identity credentials.

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? Providers will need assistance with technical infrastructure and support from technical experts.

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? Securing FHIR APIs and be compliant with privacy policies. Strengthening privacy regulations. Adopting multi-factor authentication for digital products. Build public trust and being transparent on who has access to the data, how it's going to be used and how it is protected.

PR-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? Single sign on multiple healthcare settings. Users will be verified and there will be no need to reenter biographical information. Providers will need resources to upgrade existing systems and technical expertise to support digital identity credentials. Resistance to change. Privacy and security concerns.

b. How would requiring their use improve access to health information? Health information from multiple healthcare settings will be easily accessible, enhancing treatment that can be provided. Reduce login burden to patients especially during emergencies. During emergencies, providers can have quick access to patients' records without delay of care.

c. What are the potential downsides? Lack of trust due to privacy and security concerns. Threat vectors. Healthcare settings and digital identity credentials provides can be targets. Barriers to non-technical individuals.

d. What impact would mandatory credentials have on a nationwide provider directory? Have current verified provider listings. Provide current information on the providers' specialty, location and if they are in-network or out of network. Patients can choose the providers they trust. Providers have access to other providers' information and can easily make referrals. Technical barriers for rural and underserved populations.

e. How could digital identity implementation improve provider data flow? Use of the same standard for identity and access improves workflow. Accurate and verified provider information that can be updated. Reduces the administrative burden on onboarding providers in health networks.

f. Would combining FHIR addresses and identity improve data flow? Yes, data will be correctly linked on multiple networks, data available in one standard and reduces data fragmentation, easy to access data and match a patient. Verified authorization and real-time data access.

PR-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? Educational campaigns on digital identity security. Providing resources and technical support for automating credential verifications. Complying by data privacy and security policies. Integrating FHIR and digital identity.

4. Information Blocking

PR-12. Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of electronic health information (EHI) and to promote market competition?
ASTP/ONC should continuously revise and evaluate information blocking exceptions. The exceptions are important in protecting patients' safety, privacy and enabling legitimate

operations. Revisions are suggested to prevent misuse and promote interoperability and market competition.

Provide educational materials and training, eg FAQs, case studies. This would help partners understand the exceptions. For example, have case studies on compliant and non-complaint uses of exceptions.

Have clear definition of terms being used to promote consistency in application. Clearly define terms like "substantial harm", "reasonable and non-discriminatory", and avoid ambiguity.

Provide incentives and resources on standardized based frameworks like TEFCA, and APIs, that promotes interoperability. A partner can use TEFCA knowing that it is compliant and reduce the need to rely on exceptions.

Regulate fees or licensing, revisions should be clear on caps and calculations for reasonable fees and address anticompetitive practices.

Monitor intentional and unintentional information blocking and analyze how the exceptions are being utilized. Have data on how and where exceptions have been applied and how they have created or can create barriers.

Patients can consent to share medical data, and revisions should clarify permissible disclosures under privacy laws, facilitation would be necessary on sharing data but not fully blocking data sharing.

PR-13. For any category of healthcare provider (as defined in 42 U.S.C. 300jj(3)), without a current information blocking disincentive established by CMS, what would be the most effective disincentive for that category of provider? Transparency reporting on those who block information. Penalties and enforcing restrictions on those blocking information, such as financial and access restrictions.

PR-14. How can CMS encourage providers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would it advance or negatively impact data exchange? Automation of reporting tools to detect and flag violations. Offer training on how to detect and report violations, be transparent on the reporting process and provide use cases to help healthcare organizations identify violations. It can help improve data exchange and enhance interoperability. Dispel fear of reporting by being transparent on how violations will be handled by finding ways to differentiate between intentional and unintentional violations.

D. Payers

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

accommodate all the organization and data exchange. The compatibility of systems that would be added especially from rural and underserved areas.
Provide more resources for technological advancement and compatibility with systems that are different.

PA-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?
Provide funding to programs and developers. CMS can provide synthetic data to developers to encourage exploring of innovative solutions. Developers could develop apps that connect beneficiaries with services such as transportation using demographic data. Approved solutions could receive grants or incentives or inclusion on MyMedicare.gov platform.

Expand MA star ratings to assess the utilization of APIs and points could be awarded to payers for API implementation to promote interoperability and ensuring use of the API by payers, patients and providers.

CMS can offer services from their technical experts, FHIR architects and leaders to troubleshoot issues, guide API development in accordance with the implantation guides to payers.

CMS can offer training, webinars, and workshops to payers on how to effectively apply API implementation strategies and use case studies to show the success of API adoption across different industries.

PA-3. How can CMS encourage payers to accept digital identity credentials (for example, CLEAR, ID.me, Login.gov) from patients and their partners instead of proprietary logins?
CMS should offer financial incentives and grants to assist in the cost of integrating standardized digital identity solutions with existing payer and provider systems. This could include funding for API integration and implementation.

Integrate digital identity solutions to value-base care and quality payment programs. Payers utilizing the models and achieving high levels of digital integration, provider and patient engagement should receive incentives or points or certified.

CMS should conduct pilot programs for digital integration in healthcare systems. CMS should offer technical expertise, training, documentation and support to payers and vendors during the pilot programs.

CMS should develop and continuously review implementation guides for integrating FHIR APIs with digital identity credentials that payers can leverage on.

CMS should establish certification and vetting programs for digital identity solutions that incorporate data privacy, security and protection. Payers would have clear guidelines on how to invoke privacy and security measures in there applications and have standardized data sharing agreements.

CMS should offer education and training to beneficiaries and partners in the benefits, security and privacy of using digital identity credentials for healthcare access.

PA-4. What would be the value to payers of a nationwide provider directory that included FHIR end points and used digital identity credentials? Easy access to providers, this would improve payers, patients, and provider experience increasing efficiency in service delivery. Improve privacy and security by ensuring verifications and authorized access only, this can help mitigate fraudulent activities. Integrated provider and payer system that is frequently updated with verified information. Automation reduces the administrative burden. Improve patient care and coordination if payers and providers can work together and ease the burden on the patient. Access to real-time data to determine eligibility, and the providers in network.

PA-5. What are ways payers can help with simplifying clinical quality data responsibilities of providers? Having one platform and standardized framework. Payers can collaborate with providers to improve data quality, so that providers can focus on patients.
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? Providers and payers are interested in EHR technology because this encourages real time exchange of data that will improve quality of data and reduce administrative burdens, address issues that arise with compatibility, security and technological resources needed for interoperability.

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? One platform for payers and providers can help with consolidation. Payers can leverage FHIR APIs.

PA-7. How can CMS encourage payers to submit information blocking complaints to ASTP/ONC's Information Blocking Portal? What would be the impact? Would it advance or negatively impact data exchange? Offer incentives, create awareness on information blocking and offer training. Make it easier to submit complaints through the portals, this will improve the exchange of data. The negative outcome will be complaints can exert pressure on payers and make them hesitant to share data with fear of constraints.

E. Technology Vendors, Data Providers, and Networks
This section is intended for all stakeholders to provide input on questions as they relate to use cases and workflows that involve technology vendors, data providers, and networks. While we certainly want technology vendors, data providers, and networks to answer questions in this section (and in other sections) from their point of view, we also invite all stakeholders to provide their viewpoints on the technology vendor, data provider, and network use cases as appropriate.

1. Ecosystem

TD-1. What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?
CMS should provide funding resources, this would encourage developers to test, improve and build better products. Funding will encourage new solutions that have not been in the market and start-ups will not be limited by financial opportunities.

Collaborate with both public and private partners for innovative solutions.

Expand Medicare plans Part A, B, C and D to integrate with technology products and developers can create products to be adopted by payers and providers.

Conduct Digital health products campaigns, host connectathons, conferences to improve digital health products and encourage innovation.

TD-2. Regarding CMS Data, to stimulate developer interest--
a. What additional data would be most valuable if made available through CMS APIs?
Real time data, developers can also use synthetic data to test interoperability, automation, and predictive analysis. CMS can offer sandbox environments that developers can use for sample applications and testing on patient care, cost management, telehealth, public health, reporting and monitoring.

b. What data sources are most valuable alongside the data available through the Blue Button 2.0 API? EHRs data, HIEs data, Social Determinants of Health data, providers data, payers data, public health data, research data, and telehealth/virtual data.

c. What obstacles prevent accessing these data sources today? Different standards that affect interoperability, technical limitations in integration, different regulations and policies that leads to constraints and burden partners affecting data exchange, privacy and security concerns, healthcare disparity, hesitation to change, and limited financial resources.

d. What other APIs should CMS and ASTP/ONC consider including in program policies to unleash innovation and support patients and providers? Third-party health apps, Labs and Diagnostic test, Social Determinants of Health, Behavioral Health, Telehealth, Medication, Clinical Research, Public Health Surveillance, Health Insurance, AI and Analytics.

2. Digital Identity
TD-3. Regarding digital identity implementation:
a. What are the challenges and benefits?

Challenges
Questions on privacy and data protection, centralized platform can be targets of threat vectors.

Hesitation to change. Users need to trust digital identity and transparency on data ownership and not used indiscriminately.
Accessibility barriers to non-technical users.

Efficiency and performance. A technical glitch can cause delays to essential services.

Benefits
Systematic which can avoid human errors.

Saves time when accessing services and users do not have to memorize multiple passwords.

Reduces administrative burden by automation and can save on costs too.

Mitigates fraudulent activities by providing multifactor authentication.

Access to services globally through trusted devices (can be multiple).

Users can consent to the services that they want to access and who can see the data.

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?

Digital identity can strengthen security through biometrics verifications and mitigate fraudulent activities.

Verifications can help build trust among users exchanging data, users have confidence that the parties they are interacting with have been verified.

Digital identity will require compatibility between platforms or standardized framework. Implementation requires high technical expertise.

Limited financial resources for implementation.
Digital disparity- rural communities and underserved communities may have limitations to accessing technology.

c. What impact would mandatory use of the OpenID Connect identity protocol have?
Strengthening security- verifications are done, and users can access different applications with a single sign on.

User accessibility improved, users do not have to create and memorize many passwords making it easy to access platforms.

Standardized framework can reduce login errors and developers will follow a standard form of authentication and authorization of users.

Standardized framework can enforce and consolidate data privacy and security policies. Integration requires technical expertise and financial resources that might be limited.

3. Technical Standards and Certification

TD-4. How can CMS better encourage use of open, standards-based, publicly available APIs over proprietary APIs?
Educational campaigns to create awareness on benefits of using open standards.

Have pilot projects to highlight the success of open APIs.

Training on open standards, have detailed documentation and tutorials on how to use open APIs.

Offering resources and incentives to open standards APIs to improve efficiency and capabilities.
Collaborate with partners to improve open API standards.

TD-5. How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers?
Improved patient care, patients can easily access provider information and data can be exchanged in real time eliminating duplicate services. Patients can choose the provider they trust, and the records will be available for coordinated care.

Payers could have access to data, reducing the burden to providers who can focus on patient care. Automation services can reduce administrative costs for payers and providers.

Who should publish such a directory, and should users bear a cost? It should be a coordinated effort to publish the nationwide directory.

TD-6. What unique interoperability functions does TEFCA perform?
TEFCA has established a Common Agreement
TEFCA used QHINs
Has a standardized framework and one EHR
TEFCA provides data formats and security protocols to the QHINs.

a. What existing alternatives should be considered? FHIR, Secure messaging, HIEs, Commonwell and Carequality.

b. Are there redundant standards, protocols or channels or both that should be consolidated? C-CDA, CCD, HIEs, X12, HL7v2 should be consolidated to FHIR.

TD-7. To what degree has USCDI improved interoperability and exchange and what are its limitations?
USCDI has offered standardized data classes and elements used in exchange for improving interoperability.

Improved patient access to health records by ensuring EHRs and Health IT systems comply with the standards.

Patients are more involved in their healthcare because they can easily monitor and access the health data and make informed decisions.

USCDI has provided the minimum data sets to be utilized, but data sets are still incomplete. Data fragmentation due to technological limitations.

a. Does it contain the full extent of data elements you need? It misses some elements like social determinant health data, behavioral health data, and data quality.

b. If not, is it because of limitations in the definition of the USCDI format or the way it is utilized? It is not detailed to include all data sets and the way it is utilized.

c. If so, would adding more data elements to USCDI add value or create scoping challenges? Adding data such as social determinants of health could improve utilization but interoperability issues persist because of the different ways of recording data across systems. How could such challenges be addressed? Updating USCDI and including missing data sets, improving health IT infrastructures and getting technical expertise, standardized form of recording data, providing financial resources and incentives.

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? The goal is to achieve interoperability; a balance should be achieved and the most efficient way to achieve interoperability is to adopt a hybrid approach. From unstructured input to structured output.

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

Patient data privacy and data protection/security.

Automation of health IT products and tools.

Promoting interoperability.

Secure messaging and information sharing.

Preventing information blocking.

Reporting of quality measures.

TD-9. Regarding certification of health IT:
a. What are the benefits of redefining certification to prioritize API-enabled capabilities over software functionality?
It will offer flexibility and scalability promoting interoperability.

Improved health analytics that will allow payers and providers to act swiftly on healthcare management.
It would be easier to integrate with the cloud platform.

This can improve security and data protection.

b. What would be the drawbacks? Security and privacy risks. Limited technical expertise, financial burden, bridging the gap between user focused patient care versus technology. complexity.

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)?
Standards need to expand to include structured and unstructured data, then have a standardized API.

APIs should include automated mapping of different terminologies/ codes into one standard version.

Update APIs, real-time updates for current data when dealing with different resources or data types in the whole system.

Privacy and security protections should be enforced in the APIs.

APIs should be user-friendly with easy access to quality data.

APIs should be integrated with other frameworks, HIEs, EHRs, Commonwell to encourage data sharing.

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?
Include incentives, bonuses and points to providers who utilize APIs.

Emphasize benefits of APIs when promoting interoperability, invest in training and creating awareness.

Have clear guidelines on standardized APIs certifications and implementations.

Provide technical infrastructure and support for standardized API.

Promote data quality and completeness with clear guidelines on data quality, audit data quality metrics and being transparent to the public.

e. How could EHRs capable of bulk data transfer be used to reduce the burden on providers for reporting quality performance data to CMS? What capabilities are needed to show benefit? What concerns are there with this approach? EHRs can reduce burden by automating data submission and data extraction. Standardizing data collection methods and have one reporting portal. Capabilities include showing standardized data formats, monitor data transfers and audits, streamline data needed for reporting and data collected to align to the quality measures. Strong patient privacy and data security. Concerns arise with privacy and data

security, technical expertise needed for implementation, EHRs using different standards and data quality issues in cases of incomplete data.

TD-10. For EHR and other developers subject to the ONC Health IT Certification Program, what further steps should ASTP/ONC consider to implement the 21st Century Cures Act's API condition of certification (42 U.S.C. 300jj-11(c)(5)(D)(iv)) that requires a developer's APIs to allow health information to be accessed, exchanged, and used without special effort, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws? ONC should conduct patient education campaigns on APIs health data access. Develop Apis with an equity lens to address disparities. Collaborate with other entities when developing APIs, focus on interoperability of APIs with other systems, strengthen privacy and security, fully integrate with API specifications.

TD-11. As of January 1, 2024, many health IT developers with products certified through the ONC Health IT Certification Program are required to include the capability to perform an electronic health information export or "EHI export" for a single patient as well as for patient populations (45 CFR 170.315(b)(10)). Such health IT developers are also required to publicly describe the format of the EHI export. Notably, how EHI export was accomplished was left entirely to the health IT developer. Now that this capability has been in production for over a year, CMS and ASTP/ONC seek input on the following:

a. Should this capability be revised to specify standardized API requirements for EHI export?
CMS and ASTP/ONC should have requirements for standardized APIs for EHI exports. FHIR would improve seamless exchange of data across different systems and applications. This would also reduce burden for users by offering consistency for accessing data across different systems.

Standardized API could align with existing frameworks addressing existing exceptions on information blocking to enhance data privacy and security protections.
Standardized API would reduce the cost of data migration when systems are being streamlined to a centralized platform.

Standardized API should promote patient-centric model, patients can control the use of third-party applications to manage their healthcare data from EHRs.

Standardized API promotes interoperability that leads to high data quality. Developers can leverage on better quality data to invent new apps that could be used for research, care coordination and personalized decision support.

b. Are there specific workflow aspects that could be improved?
Automation of EHI export, this would improve status tracking and notifications.

Clear guidance on how to troubleshoot and resolve export issues errors

Design user-friendly interfaces. EHI exports should be user-friendly within the health IT systems.

Flexibility on choosing data to export. Standardized APIs can help with flexibility. streamline the authorization and security for EHI export to enhance the existing safeguards.

c. Should CMS consider policy changes to support this capability's use?
CMS should have clear requirements for EHI export API standards in implementation guidelines.

CMS should support pilot programs that test and evaluate standardized EHI export APIs to gather real world data for policy review.

CMS should offer incentives within quality programs for partners to adopt and use certified standardized EHI export API.

CMS should promote public awareness and education for providers and patients about the benefits of EHI export and its capabilities.

CMS should integrate EHI exports to value-based care models, the patient population data can be analyzed by users for quality improvement.

CMS should enhance data governance, data privacy policies and security protections for EHI data export.

CMS should continue collaborating with different partners to address disparity issues, evolving needs and challenges.

4. Data Exchange

TD-12. Should CMS endorse non-CMS data sources and networks, and if so, what criteria or metrics should CMS consider?
CMS can collaborate with non-CMS networks after they set clear guidelines for requirements and standardized data sources for easy interoperability and address data quality, privacy, and security concerns.

CMS should endorse more data sources that should be in use in value-based care models, the data sets can identify high-risk patients and providers can leverage the information for success in these models.

CMS should promote the streamlining and automation of external data sets that can be used in reporting. This will reduce the burden on providers by minimizing manual extraction and submission of data. It can also improve research on diseases and new treatments.

CMS should actively promote interoperability and seamless data exchange. Having standardized formats would encourage data sharing in the healthcare settings.

CMS should endorse HIE, registries, patient-reported data for an all-inclusive and complete view of patient health.

TD-13. What new opportunities and advancements could emerge with APIs providing access to the entirety of a patient's electronic health information (EHI)?
Improved healthcare management in terms of better patient care and clinical outcomes. Care coordination and smooth transitional care.

Embracing technology in healthcare might expand opportunities for extensive and new research in addressing healthcare concerns.

Patients can use integrated apps to gain deeper insights into their health care management, progress and make informed decisions.

Leveraging AI in clinical decision support. AI can provide personalized health care recommendations, flag issues and suggest treatments based on patient's profile.

Improved public health surveillance. Complete EHI data can provide real time information on disease outbreaks and population health enabling faster response.

Standardized APIs promote interoperability between different systems, improving the quality of data and enabling seamless exchange of data across the healthcare system.

a. What are the primary obstacles to this?
Limited financial resources, new infrastructure, and implementation of the standardized EHI API can be costly for healthcare organizations.

Health equity to underserved and rural communities to address health disparity.

Enhanced data privacy and security protocols are essential to protect patient sensitive data from unauthorized access, misuses, and breeches.

Standardizing EHI API across all systems for seamless data exchange to address the different standards and protocols in healthcare settings.

Continuous review and evaluation of information blocking regulations to ensure healthcare providers and vendors comply with sharing of information/data.

Patient digital literacy, patients need to understand their data privacy and security rights, and how to effectively use the apps for healthcare management.

b. What are the primary tradeoffs between USCDI and full EHI, especially given more flexible data processing capabilities today?
EHI contains a larger scope of healthcare data as compared to USCDI that has standardized data elements, it is easier to operate USCDI than EHI with a large data set.

EHI can be costly to implement and manage because of the richness in data as compared to USCDI that is easier to implement with lower costs because of the standardized elements.

EHI needs to invest more in data and security because of the detailed data and handle sensitive data, it is easy to comply with regulations with USCDI.

Smaller organizations find USCDI cost efficient as compared to EHI because of the infrastructure and tech expertise needed for configuration and management.

TD-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? The endpoint is connected to public health registries, state health departments, labs, and healthcare providers. Types of data include immunization records, lab results, public health and disease alerts. For different departments local and state levels are covered, but the whole organization covers national level. Searches can be done with Organizational IDs and NPIs for healthcare providers.

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

c. Do you interconnect with other networks? Under what frameworks (for example, TEFCA, private agreements)? Interconnect with local, state, national and international networks. Eg National Health Information Network (NHIN), Health Level 7 (HL7), National Electronic Disease Surveillance System (NEDSS), international networks like WHO, states HIEs, states department public health network.

TD-15. Regarding bulk FHIR APIs:
a. How would increased use of bulk FHIR improve use cases and data flow?
Bulk FHIR improves interoperability, bulk data exchanged across systems in standardized FHIR format promotes seamless exchange of data across different systems.

Automation reduces provider burden and improves patient care. Standardized and automated data collection reduces manual errors and improves data quality.

Improve healthcare organization responses to public health agencies reporting, public health can collect and analyze patients' data, detect outbreaks in diseases, and intervene promptly.

Improve research, standardized bulk data collection allows for aggregation on data from multiple systems, promoting collaboration research efforts among organizations.

Processing large data sets can reduce operational costs of handling large data sets.
Bulk FHIR can be integrated with AI to perform predictive analysis for diagnosis, treatment and risk assessment.

Value based care models can use bulk data to analyze patient populations and improve the quality of patient care through the models.

b. What are the potential disadvantages of their use?
Data and privacy challenges- Bulk FHIR exports large data sets and raises data privacy concerns with PHI. Strict data privacy and security policy regulations are to be enforced. Challenge in handling multiple regulations to comply with strong data privacy and security.

Different standards used by organizations can lead to data quality issues, integrating Bulk FHIR with other systems can be a technical challenge in data mapping and transformations.

Limited resources for implementation and infrastructure, bulk FHIR implementation requires technical expertise in FHIR, cloud infrastructure, and modern web technologies. Health organizations that are in underserved areas, rural areas or are smaller can lack this expertise and infrastructure.

Data quality issues if the source of data is poor in quality or fragmented data. Bulk FHIR will inherit the issues and not automatically fix them.

Configuration and management challenges, Bulk FHIR processes large data sets that need good network bandwidth, if not effectively managed it can affect other systems, hinder productivity and jeopardize data privacy and security.

TD-16. What are the tradeoffs of maintaining point-to-point models vs. shared network infrastructure?
Individual connections can lead to better security in point-to-point if the network is not large. Shared networks have stronger and advanced security needs.

Point-to-point has high performance because on individualized bandwidth but not efficient for a large network, shared network can have traffic due to shared bandwidth but efficient for a large network.

Point-to -point needs more maintenance and infrastructure is more costly than shared network infrastructure.

Point-to-point needs separate connections for the systems, shared network you just leverage on the existing system.

Point-to-point as a simple design with less connections, additions can lead to complexity, shared network is complex in design.

Any modifications or additions in point-to point require new connections, shared networks leverage on existing connections.

a. Do current rules encourage scalable network participation?
Current rules encourage Infrastructure sharing,

Net Neutrality, the internet market is open and promotes innovation, developers can create apps and launch them. All internet traffic is treated equally and there is no interference.

Cloud accessibility can reduce costs of infrastructure, and access more tools and services. Cloud services can transcend geographical limitations; with internet connection it can foster collaboration globally.

Standardization of open standards like TCP/IP, HTTP have promoted interoperability between different systems and improved communication.

Partner agreements encourage scalable network participation.

b. What changes would improve alignment (for example, API unification, reciprocal access)?
Advocate for standardized API, have consistent guidelines, standardized endpoints, common authentication and authorization mechanism and uniform pagination.

Have centralized API documentation with clear guidelines for testing and exploring APIs.

Mandate reciprocal access have standardized frameworks that are easy to understand and implemented by all users. This promotes transparency, easy access and control over users' data.

Encourage open-source networking, collaborate with partners across the industry to promote open-source APIs, standards, and data models.

Unified payers' platforms can provide a constituent endpoint for payers to integrate with providers and beneficiaries.

Universal interoperability standards across the industry. This would allow for easy integration of data. FHIR would promote easy data mapping and transformations.

Implement strategies for versioning and back compatibility to minimize disruption for standardized APIs.

TD-17. Given operational costs, what role should CMS or ASTP/ONC or both have in ensuring viability of healthcare data sharing networks, including enough supply and demand, that results in usage and outcomes?
CMS should provide financial support, reimbursements, and incentives to value based care models and quality payment programs to encourage data sharing technologies and practices practice.

Enforce universal interoperability standards by defining technical standards and governance.

Align and consolidate, governance models, data privacy and security policies for secure data exchange on the cloud and open sources. For example, advance the goals of the 21st Century Cures Act.

Conduct educational campaigns for users to create awareness of the importance of data sharing.

Collaborating with partners to promote seamless exchange of data to promote better patient care, comprehensive patient data records, improved care coordination and public health surveillance.

5. Compliance
TD-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?

Requested records but received minimal information in the dataset. Received partial data that was not beneficial for the project. This affected the data quality and completeness of the data.

Health care organizations not honoring business agreements when it comes to sharing data for public health analytics. Communication stalls, unanswered calls, ignored meeting requests. This affects the exchange of data necessary for projects.

Heavy costs associated with accessing data. The cost of obtaining clinical data sets can be a financial burden to smaller organizations.

Lack of API documentation, technical required documents, or support. EHRs not providing requested data through multiple requests.

Challenges with some partners who do not want to share data because they want to make profits, or they insist on using their own platforms.

Reluctance in sharing data, it takes a long time to get data sets stalling the project. When moving to production, and healthcare organization delays providing data without valid explanations or alternative solutions.

Receiving data in different standard formats other than the other requested. For example, receive custom xml and had requested FHIR. This requires data mapping and transformations. This can be time-consuming and cause delays to projects.

Fragmented data and incomplete data from diverse sources. When querying for patient resources, the API can return incomplete data due to different standards used even if the information is available in the EHR.

Provider documentation is outdated and makes the API encounter errors, for example 404 errors. The provider is slow to respond on request; troubleshooting is challenging as the provider attributes the problem to be originating from our side without investigations.

Limited access to vendors or providers sandboxes. Takes a long time to have access to sandboxes delaying testing of solutions.

b. What additional policies could ASTP/ONC and CMS implement to further discourage healthcare providers from engaging in information blocking practices?
Public reporting of violations. Create a database for information blocking complaints, the actors after investigation, resolution, and recommendations.

Clear definitions and guidelines on interoperability. Continue to refine the use of standardized APIS (FHIR) and standard data models for data exchange. Offering incentives, bonuses and points for promoting interoperability in value-based care models for providers who perform highly in data exchange with partners and patient engagement.

Develop a star rating system for healthcare providers that promotes interoperability and adherence to information blocking principles.

Support rural and underserved communities to invest in IT infrastructure and training to support seamless data exchange and overcome technical barriers.

Advocate for national data-sharing networks.

Enhance, align and consolidate data privacy and security regulations. Multiple data privacy and security regulations should be unified and standardized.

Have strong deterrent measures for persistent information blocking organization. For example, the organizations cannot have access to federal programs.

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?
Rural, underserved, and small healthcare providers who are not part of QHINs
Non-Certified Health IT vendors

TD-19. Regarding price transparency implementation:
a. What are current shortcomings in content, format, delivery, and timeliness? Hidden costs in patient care and price fluctuations over short periods of time leading to unexpected patients bills, complexity in understanding insurance coverage and costs, lack of simple or plain language for understanding costs, services not covered or performed out of network services misleading on costs. Delayed response of healthcare professionals or payers. Misleading information on other cost-effective procedures. Delay in providing information and services due to biasness. Lack of standardized conventions for payers makes it difficult to link datasets that are crucial for understanding cost drivers. Healthcare providers rely on third-party vendors, this adds cost and causes another layer of abstraction. Payers do not update their systems frequently leading to outdated information and misinformation. Lack of standardization for billing codes across different systems makes it hard to compare prices among diverse providers.

b. Which workflows would benefit most from functional price transparency? Payers' coverage verification and eligibility to services, pre-service and post-service cost of health care services – emergency, urgent and specialty care, chronic disease care, medication costs and

prescription billing, healthcare billing standardization. Financial counselling-Financial counselors could provide more guidance to patients on financial responsibility. Value based care – providers to be paid for quality of service rather than quantity.

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

Patients

Improve access to preventative care, advocate for indiscriminate quality patient care and seamless communication among care givers to personalize treatments, transparency in the cost of health services and conditions, utilize telehealth/virtual services.

Providers

Improved interoperability of electronic health records to provide a comprehensive view of patient information, automation of administrative tasks to reduce time used in performing the tasks and focus on patient care, train more healthcare professionals to assist the existing workforce and offer benefits that address caregiver stress and burnout, encouraged use of digital tools for detecting anomalies like high blood sugar or emergencies, leveraging AI for data analytics to identify patterns, predict patient needs, outcomes and improvement.

Payers

Automating claims process, integrated systems to make it easy to access patients' data on services provided to coordinate billing.

d. What would further motivate solution development? Offering incentives, points, reimbursements and bonuses to providers that use health technology to support the implementation of technological tools and enhance workflows, exploring value-based care that incentivize high quality patient care to contain costs and improve population health, encouraging the use of open standard based technologies to improve interoperability, educational campaigns creating awareness on digital products and the benefits, invest and leverage on data analysis and metrics to identify gaps in healthcare and continuous improvement. Promote health equity by developing guidelines and policies that address health disparities by including social determinants health data.

F. Value-Based Care Organizations

This section is intended for all stakeholders to provide input on questions as they relate to use cases and workflows that involve value-based care organizations. While we certainly want value-based care organizations to answer questions in this section (and in other sections) from the value-based care provider point of view, we also invite all stakeholders to provide their viewpoints on the value-based care workflows as appropriate.

1. Digital Health Adoption

VB-1. What incentives could encourage APMs such as accountable care organizations (ACOs) or participants in Medicare Shared Savings Program (MSSP) to leverage digital health management and care navigation products more often and more effectively with

their patients? What are the current obstacles preventing broader digital product adoption for patients in ACOs?
Reimbursements to ACOs that encourage the use of digital tools, for example remote monitoring can prevent emergency room visits. Remote check-ins can assist with chronic disease management.

Offers incentives to automated reporting and encouraging use of digital health metrics in quality measures. Quality measures can improve provider-patient communication and patient satisfaction.

Funding educational campaigns to create awareness of importance and benefits of digital health tools. Education can promote preventive care through screening and immunizations preventing serious conditions.

Offering grants, reimbursements and incentives to support organizations to upgrade older systems to support interoperability.

Digital health options expand the markets for ACOs, patients can be attracted to modern healthcare solutions.

Standardize information blocking regulations and promote seamless exchange of information that provides comprehensive patient information.

Obstacles
Limited technical expertise to configure and manage the infrastructure. Integrating new technology with existing systems can be technically challenging, require implementation in stages, and time-consuming.

Limited sources of funding for the infrastructure, software, hardware, training and integration can be expensive for ACOs within smaller practice, underserved areas and rural areas.

Different organizations use different systems and standards that can create data silos and affect data exchange effectively across the entire ACO.

Hesitation to change. Providers can be hesitant to try new workflows that would require them to change their practice and prefer the traditional workflows.

Digital disparity, especially in rural and underserved communities. Lack of digital literacy and equal access to technology can lead to disparity in the use of digital products in certain populations.

Patients may have concerns about data privacy and security and be reluctant to share sensitive information. Maintaining compliance with data privacy and security require enhanced regulations and continuous reviews.

Digital products should be user friendly, if they are complex users will have a challenge utilizing them and not adapt to them.

VB-2. How can key themes and technologies such as artificial intelligence, population health analytics, risk stratification, care coordination, usability, quality measurement, and patient engagement be better integrated into APM requirements?
AI can be used for predictive analysis; the data can be used to identify at risk populations, forecast individual health needs and patient population outcomes.

AI can also improve scheduling with less errors, timely alerts and better communication.
, this can support care teams in coordinating care.

Technology can assist with smooth transition of care coordination between multiple facilities and providers.

AI can be integrated into quality measurement to reduce the burden on reporting and predict quality issues.

Technology encourages users to be involved and actively participate in patient care management. APM can promote digital products and AI to users through educational campaigns and training.

APM can promote interoperability and seamless data exchange in diverse healthcare settings. This can improve care coordination and patient care.

APM can Incentivize the inclusion of social determinants of health data into risk stratification models and AI can analyze the data to identify patients' risks.

APM should invest in the training and provide ongoing technical support to healthcare professionals to utilize technology as an asset.

APM should develop clear guidelines and standards on the use of AI in healthcare and enhance data privacy and security frameworks to build trust among users.

VB-3. What are essential health IT capabilities for value-based care arrangements?
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.
Care planning, patient event notification, data extraction, quality performance measurement, access to claims data, patient ID matching, remote device interoperability, population health management, telehealth/ virtual visits, secure messaging, scheduling appointments, health management and education resources, referral services, and community support services.

b. What other health IT capabilities have proven valuable to succeeding in value-based care arrangements? Social Determinants of Health integrations, utilize Artificial Intelligence

and Machine Learning, enhance data privacy and security, universal robust EHR, promote interoperability and revenue cycle management systems.

VB-4. What are the essential data types needed for successful participation in valuebased care arrangements? Clinical data, claims data, Social Determinants of Health Data, patient specific shared data, healthcare cost data, quality metrics data, risk stratification and assessment data.

2. Compliance and Certification

VB-5. In your experience, how do current certification criteria and standards incorporated into the ONC Health IT Certification Program support value-based care delivery?
Standards are assisting in promoting interoperability, FHIR, USCDI, C-CDA are supporting seamless data exchange across systems.

The 21st Century Cures Act is helping to prevent Information Blocking, ONC ensures that information is shared freely to support collaboration and informed decision-making.

Mandated reporting of eCQMs. These measures are integral to initiatives like the MIPS and APMs, both of which are designed to incentivize healthcare providers. Value- based care tie reimbursement to quality outcomes.
Health IT and certifications capture detailed demographic, clinical and social data that is crucial for population health management and helps in identifying health disparities.

Value based care helps providers to identify areas of improvement in patient care and promotes patient engagement by enhancing provider-patient communication through secure messaging.

Supporting continuity of care by giving guidelines on smooth care transition through Clinical Decision Support (CDS).

ONC mandates compliance in testing, certified health IT developers conduct annual testing to demonstrate that their products function as intended in healthcare settings.

VB-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?
Consolidate data from different resources from public and private entities. APMS need to aggregate data from long term care, behavioral health, Social Determinants of Health, Remote monitoring, and Patient-Generated Health Data.

Use of advanced technology for analysis. (AI and ML). For example, advanced tools to help identify patients with social barriers and are at high risk with poor health management.

Use universal standards and automate data to promote interoperability and exchange of data across systems for quality patients' data.

Enhance data privacy and security for patients consent on data sharing across APM systems, building trust and ensuring privacy while improving patient care.

Advance care team coordination by making patient care details accessible to care team members with clear roles and responsibilities for care to be provided to patients.

APMs require integrated financial and clinical data systems for measures of the total cost of healthcare, to help in financial analysis and management.

APMS requires automated data collection and submission for performance measurement and reporting in value-based care models. This can provide real time feedback to providers to measure performance against APM benchmarks.

VB-7. How can technology requirements for APMs, established through CEHRT or other pathways, reduce complexity while preserving necessary flexibility?
Promote use of universal standards and universal frameworks. Emphasize the importance of open, standards APIs, FHIR for seamless data exchange and allows for different systems to communicate easily.

Establish universal standards for data quality, privacy and governance within APM exchange.

Consolidating data models leads to a common data model for data aggregation and analysis.

Automation of data to reduce burden on reporting. Design workflows with the user in mind and reduce administrative burden. For example, simplify data submission processes for APM reporting through automation and direct integration with reporting platforms.

Offering incentives and funding resources. APM should incentivize providers who have adopted technology that support value-based care.

APM should conduct educational campaigns and training. Provide technical assistance and education to providers to implement technology and reduce complexity.

VB-8. How can other HHS policies supplement CEHRT requirements to better optimize the use of digital health products in APMs?
Policies that promote API standardization can integrate with CEHRT to improve real-time data flow promoting improved patient care. FHIR APIs have better integration with digital tools supporting interoperability.

Advance digital identity policies to streamline and enhance data privacy and security.
Expand TEFCA participation to all entities to facilitate secure and seamless data sharing across diverse health care settings.

Provide resources for education and technical assistance/support for implementation of digital health products in APMs and address challenges to workflows, integration and data access.

Automate reporting to reduce burden on providers by promoting digital quality measurement and value-based care. APMS get incentives to leverage digital health products for automated data capture and reporting.

Promote patient engagement by having user friendly digital tools that allow easy access to health information and communication.

Promoting 21st Century Cures Act to mitigate information blocking and enhance care continuity through data being exchanged freely.

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?
Lack of universal standards, healthcare providers can use different EHR vendors, HIEs and digital products affecting interoperability and data quality.

APMs lack universal provider directories that might affect smooth transition of patient care, the care givers have communication challenges with the care coordination team because of the complex system that lacks up to date and accessible providers directory.

Lack of clear understanding of APM requirements and eligibility of receiving notifications. Mandate is not explicit in sending notifications to all APM participants. Larger healthcare settings might have established connections to ADT feeds, but smaller practices or individual providers may not have direct, real-time interfaces to capture notifications from hospitals.

Challenges with workflow automation and integration. Exchanged data needs to be in a common data model/format. Variability in data fields, coding and the level of detail can pose as an integration challenge to APM participants.

APM participants that do not have automated workflows might experience administrative burden due to lack of IT infrastructure to automatically ingest, process and route notifications leading to manual process and delays.

Smaller APM participants with limited resources can struggle to bear the costs of IT infrastructure, including subscriptions to notification services.

Data privacy and security concerns arise when wanting to share information, concerns about secure transmission and receiving of sensitive information.

VB-9. What technology requirements should be different for APM organizations when comparing to non-APM organizations (for example, quality reporting, and interoperability)?
APM organizations should focus on efficient and advanced data analytics tools integrating AI, ML and cloud services.

Promoting interoperability – operate with unified data systems for seamless exchange of data done through robust interfaces (FHIR APIs, HIEs).

Use of digital products to improve patient care. Third party health apps, telehealth, patient portals.

Automating reporting and data collection for eCQMS. Automatically gather performance measure data from EHRs.

Advanced and efficient financial management tools. Integrate payers systems with patients' and providers' applications.

VB-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?
Establish common data models for seamless exchange of data. Evaluate USCDI to include more data sets and continue to promote utilization of FHIR APIs.

Continue promoting interoperability, and implementation IT infrastructure in phases while also providing technical assistance and training.

Collaboration with all partners, providers, health IT vendors and patients to evaluate and continue improving the needs of healthcare system.

Enhance patient portal functionalities like secure messaging, access to test results, coordinated care plans for chronic diseases.

Advanced data analytics.AI can be integrated in automated quality measures to collect data and report eCQMs to APM.

Enhance data privacy and security measures/ policies. Improve how sensitive data is being handled while also facilitating efficient ways for information sharing to address data privacy concerns. For example, advanced access controls and auditing capabilities.

Integrate Social Determinants of Health Data with clinical data in the applications for a holistic patient view and improve patient care.

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?
Provide funding resources and incentives to underserved and rural areas Resources can be provided to help with the costs of adopting and integrating CEHRT. Collaborate with federal

programs that target rural and underserved communities to improve health care and expand financial avenues.

CEHRT should leverage on interoperability and data exchange to facilitate data sharing across diverse systems, improve accessibility of data, improve patient engagement and satisfaction.

Provide technical infrastructure and technical support through expanding the existing programs like Quality Improvement Direct Technical Assistance (MQIDTA). Programs can assist with training, building technical documentation, and enhancing workflows.

Provide training on CEHRT requirements and do pilot projects to do real world testing focused on rural or underserved communities.

Collaboration with larger health centers or participate in APMs, this will promote sharing of resources and have real-word case studies of CEHRT requirements.

3. Technical Standards

VB-11. What specific interoperability challenges have you encountered in implementing value-based care programs?
Different data formats that result in data fragmentation affecting data quality.
Interoperability challenges dealing with different systems due to lack of standardized data formats.

Lack of universal standardization for payers. Payers have different submission and reporting requirements, leading to a lot of challenges when dealing with multiple health plans.
Limited financial resources to support interoperability. Smaller health care settings struggle with the cost of maintaining the technical infrastructure, EHRs, HIEs affecting data exchange and interoperability.

Data overload due to high data volume from multiple tools, systems struggle to integrate data.

Healthcare providers can be hesitant to change. Adopting new technology might be a hurdle because they are used to the traditional legacy systems and they can interpret it as a burden because they need to learn new technology.

Data privacy and security concerns. Data privacy and security policies must be enhanced to address concerns on data sharing and unauthorized access. How to handle patient consent across divers systems should also be fine-tuned.

VB-12. What technology standardization would preserve program-specific flexibility while promoting innovation in APM technology implementation?
Using universal open standards. APM should give clear guidelines and define common data models and formats in the standards.

APM should have standardized quality measure reporting requirements.

APM should have standardized technical guides and documentation for reference.

VB-13. What improvements to existing criteria and standards would better support value-based care capabilities while reducing provider burden?
Standardize quality measures to reduce burden by consolidating the multiple quality measures from different parties.

Promote enhanced interoperability to improve seamless exchange of data across diverse healthcare systems and provide a comprehensive patient information.

Use advanced data aggregation and analytics tools. AI can be used for predictive analysis on population health to improve quality of care. AI can also be used for documentation, generate clinical notes during visits and collect necessary data.

Automate reporting and data collection. Data can be pulled automatically from EHRs reducing provider burden by minimizing need for manual entry.

Use advanced financial management tools to integrate payers' systems to patients' and providers systems.

Provide technical assistance and training to providers on health IT infrastructure, eg EHRs to maximize efficiency and address issues like staff burn-out.

Partnership between private and public entities to utilize value-based care models. Entities that use these models can be incentivized or get points to promote effective care coordination across different systems.

VB-14. How could implementing digital identity credentials improve value-based care delivery and outcomes?
Digital identity would improve patient identification through verification; this would help with having correct patient records and reducing errors.

Correct patient matching can reduce duplication of tests and procedures. This can cuts costs for the patient and improve care coordination for better patient care outcomes.

Reduces time used to access medical records, especially during emergencies because all records can be accessed with a single sign on. Patients do not have to memorize multiple passwords.

Patients have more control over data and who they want to share with. This can foster trust and transparency and improve patient engagement and satisfaction.

Digital identities can utilize biometrics that creates an additional layer to secure patient data and prevent unauthorized access. This can also help to mitigate healthcare fraud and misinterpretation of credentials.

Digital identities have improved accessibility. Patients can easily have secure access to digital applications, like telehealth services, access patient portals and integrate with other systems if the patient consents to it.

VB-15. How could a nationwide provider directory of FHIR endpoints help improve access to patient data and understanding of claims data sources?
Having a centralized platform for common data exchange can reduce data fragmentation and enhance data quality. The directory would promote seamless exchange of data through the standardized access points.

FHIR endpoints would connect to claims data enabling the patient and providers have access to billing information on services provided.

Providers can search what other providers or entities are complaint with FHIR, collaborating with each other for seamless exchange of data.

Real-time access to data. Nationwide directory will improve accessibility across multiple providers, make data easily accessible, enhance patient care and decision making.

Improve research, it will be easy to access data for research in a centralized platform. Data is integrated from multiple sources in the central platform and researchers can easily access combined clinical and claims information.

Can improve patient engagement and satisfaction. Patients can use the directories to search for providers or connect apps to provider systems to access and manage health information.

What key data elements would be necessary in a nationwide FHIR endpoints directory to maximize its effectiveness? FHIR resources can include Capability statement, Endpoint, Organization, Location, Practitioner role.

Having Endpoint details – Endpoint URL, Endpoint type (patient, provider, payer, public health, research), FHIR version supported, status, managing organization, name.
API documentation and resources, search filters.

Provider or entities details – Provider name, identifiers, type, contact information, location. privacy and security-authentication methods, certificate information/public key.

Data accessibility and permissions, operational metadata, geographic and jurisdictional details, interoperability standards, define users.

III. Collection of Information Requirements
Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is

required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award.

Further, CMS and ASTP/ONC are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. CMS and ASTP/ONC note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, CMS and ASTP/ONC note that we will not respond to questions about potential policy issues raised in this RFI. CMS and ASTP/ONC will actively consider input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the Government for program planning on a non-attribution basis.

Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received or a summary of those public comments.

Stephanie Carlton, Deputy Administrator of the Centers for Medicare & Medicaid Services, approved this document on May 9, 2025.

Steven Posnack, Acting Assistant Secretary for Technology Policy, Acting National Coordinator for Health Information Technology, approved this document on May 6, 2025.

Robert F. Kennedy, Jr.,
Secretary,
Department of Health and Human Services.

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