Cover Letter

Submitted To:
Centers for Medicare and Medicaid Services (CMS), Assistant Secretary for Technology Policy (ASTP) and Department of Health and Human Services (HHS)
Attention: CMS-0042-NC
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Accenture Federal Services LLC, 1HealthSciences, and Health Level Seven (HL7) are pleased to be working together on this response. We appreciate the opportunity to respond and look forward to supporting the next phase of digital health modernization across the federal landscape.

Accenture Federal Services LLC (AFS), a wholly owned subsidiary of Accenture LLP, is a US-based company with extensive global health experience. Accenture supports eight of the top 10 U.S. health insurers, serving over 150 million members, including the processing of 170+ million claims annually (including Medicare and Medicaid), and the updating of 20+ million provider records. Accenture uses a combination of cloud, data, AI, and EHR (Electronic Health Record) technologies to transform healthcare delivery. Our customers use our modern solutions across virtual care, cloud-native applications, interoperable systems, Generative AI and personalized care experiences to address challenges such as workforce shortages, rising costs, and the demand for more accessible, humanized and personalized care.

1HealthSciences is a company formed by a group of experienced physicians, clinicians, data scientists, and technologists. Over the last 35 years, these entrepreneurs have founded numerous successful healthcare information technology companies and have completed some of the largest, most extensive healthcare system optimization projects ever undertaken. The company's revolutionary next chapter uses Cognitive AI to deliver a single, individual-centric, integrated informatics platform that finally solves the long-vexing semantic interoperability problem in health. For the first time, all data is understandable and computable, delivering comprehensive, empirically true information from all sources to providers, patients, and researchers.

Health Level 7 (HL7) is a not-for-profit, ANSI-accredited standards development organization (SDO) dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information to support clinical practice and the management, delivery, and evaluation of health services. This includes the development and support of standards such as HL7 Fast Healthcare Interoperability Resources (FHIR)®, which enable faster and more effective interoperability of systems across health care, a key priority of public and private sector leaders.

Thank you again for the opportunity to contribute to this Health Technology Ecosystem RFI.

Regards,

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Executive Summary

CMS-0042-NC Request for Information (RFI) defines the Centers for Medicare and Medicaid Services (CMS)'s needs to operationalize a health technology ecosystem that is person-centered, standards-based, secure, and capable of supporting innovation at scale. This response aligns with that goal and offers a structured path that draws on existing policy, modern technical foundations, and real-world implementation experience.

CMS has one of the largest healthcare datasets in the world used for mission-critical operational activities. We now have the opportunity as an industry in partnership with CMS to transform this data into structured, semantic components that align perfectly with CMS rules, patient benefit models, and longitudinal care goals. Our recommendations are based on semantic fidelity, standards-based scalability, and real-world accessibility for patients and caregivers alike. These essential CMS goals are to be achieved by considering the following criteria:

- Creates a member-centered knowledgebase of semantically understood data elements
- Does not replace, instead enriches, current HIEs, EHRs, and Blue Button 2.0
- Does not initially fully depend on connecting with and aggregating EHR data
- Rapidly creates usable and semantically true clinical information from CMS claims

The data infrastructure at CMS can be used to generate a person-centric view of data, simultaneously benefiting patients, caregivers, providers, care teams, payers, and researchers. Additionally, building a semantically robust digital foundation allows CMS to continue to explore responsible generative AI applications using a combination of CMS data and human led oversight.

We share CMS's view that while the infrastructure for health information exchange is largely in place, the priority now is to activate it in ways that deliver measurable public value. This includes making data accessible in usable forms, enabling responsible use of automation, and reducing complexity for systems built around patients and providers. Our recommendations aim to help CMS move from infrastructure readiness to ecosystem utility. This endeavor requires sophisticated data treatment that must support:

- Data de-duplication that discerns and assimilates data sourced from different venues
- Data sequencing that cognitively and clinically organizes data that is received over time
- Data understanding to semantically curate each data component and transform it into contextually verifiable content

In addition, this submission reflects CMS goals for patient-centric longitudinal data, practical generative AI integration, scalable trust frameworks, as well as an infrastructure that supports both clinical realities and individual rights. Each major area will be addressed in this RFI.

Patients and Caregivers

PC-1 Helpful Health Management and Care Navigation Applications

The most helpful health management and care navigation applications not only present static data but also interpret structured claims and clinical data, enabling beneficiaries and caregivers to act confidently using an “at a-glance” consolidated view.

Useful health management and care navigation applications consist of the following:

- Patient-centric support that eliminates segmented information, silos, and barriers
- Care timelines built from claims, encounters, and enrollment data
- Notifications for preventive services based on age, history, and condition
- Service information and its impact on remaining benefit eligibility
- User-friendly, contextualized, and actionable medical and administrative data for patients
- Quality benchmarks that signal where areas are not met or have insufficient documentation

Key components to achieving helpful health management and care navigations applications are:

- Applications operated on semantically structured data using HL7 FHIR. Outputs align with CMS policy and are made available through SMART On FHIR application programming interfaces (APIs)
- Applications that consist of comprehensive data gathered from clinical and insurance information as well as claims, eligibility, and comparison information
- Applications that use Trusted Exchange Framework and Common Agreement (TEFCA)-enabled secure exchange of records, enabling transformation of TEFCA-acquired data into FHIR-native, policy-aligned structures that support real-time reasoning

PC-1.a and PC-1.b Support from Digital Health and Health Assistant Software

For digital health products to enable and support patient health, patients and caregivers should have a complete view of care, provider, and insurance information. This includes:

- Medications prescribed/recommended by providers (to include side effects and interaction warnings)
- Conditions across providers with links to consumer-friendly content that explains personalized next best actions
- Lab and imaging test results from venues, with narrative reports and comparisons to historical data
- Contact information for physicians and caregivers
- Near real-time data from digital home devices (e.g., glucometers, blood pressure monitors)
- Documentation of non-digital information (e.g., weight, temperature, observations)
- Online prescription refill requests and appointment scheduling information
- Information about patient use of “ask-a-question” support from a healthcare provider

This information will enable digital health products and personal assistance software in the future

in activities such as:

- To support seamless care across organizations
- Confirmation of chronic condition management steps (labs, appointments)
- Comparison of personal care to recommended guidelines
- Proper alignment of diagnosis and procedure codes
- Detection of duplicate submissions and the support to resolve these issues
- Identification of potential drug interactions
- Benefits tracking (particularly under Medicare Advantage)
- Prior authorization status and appeal outcomes

To enable these features, digital products must use structured reasoning logic that connects raw data to care expectations, quality measures, and CMS benefit rules. Visual tools provide intuitive user experiences that help patients manage their health and coverage more effectively.

PC-2 Access to Health Information in One Location

Complete health information is not accessible from a single location as patients regularly see multiple providers. This results in separate health records supported by different electronic health records (EHRs), patient portals, login IDs, and passwords. In multiple locations, even in which the same EHR is used, there is often siloed data.

CMS can change this by offering a longitudinal health record derived from Medicare Fee-for-Service (FFS), Medicare Advantage, Medicaid claims, and enrollment data. This record must be built using structured, validated, and semantically aligned HL7 FHIR resources. Patients and caregivers should be able to access it securely via SMART On FHIR applications, with controls that reflect privacy and role-based access rules.

PC-2.a and PC-2.b Workflows Where Comprehensive Health Data is Helpful

Patients and caregivers need the following comprehensive data to make informed healthcare decisions:

- Centralized access to all claims, appeals, authorizations, denials, services requests, plan-specific coverage requirements, medication history, enrollment data, and follow-up referrals are essential for safety and continuity
- Chronic conditions require the tracking of services, tests, and procedures across different providers and require long-term planning to stay on prescribed schedules
- Beneficiaries who are enrolled in both Medicare and Medicaid must be able to reconcile benefits, enrollment rules, and service use across two systems that often operate independently
- A single data source with interpretive capabilities for benefits and cost planning is key. Particularly during open enrollment season, this is needed to provide information about historical service use, for plan benefits comparisons, and for expected out-of-pocket cost forecasting

Technical capabilities necessary to enable informed healthcare decisions:

- Health information technology that delivers transformational value by making disparate data about beneficiaries faithfully interpreted and understood so that transformed data can be used effectively across workflows, applications, platforms, and organizations
- Provision of a unified portal or data sharing capability, built on semantically structured HL7 FHIR data that allows patients and caregivers information they need to improve their health, without needing to switch between disparate platforms or manually reconcile information
- Enabling flexible presentation and sharing of data that adapts by role (patient vs beneficiary vs caregiver), language (English, Spanish, etc.), and data presentation interface (patient direct presentation vs API-based data sharing)

PC-2.c Unavailable Data Types and Obstacles for Health Data and Finding Care

Several data types remain difficult to access through patient-facing portals or digital health applications. These include diagnostic imaging and test results, clinical notes and discharge summaries, authorization status, referral tracking, and Medicaid service data. Obstacles to accessing this information electronically include:

- Lack of standardized data structuring, which creates difficulty for consumer applications to aggregate and interpret information from different sources
- Limited functionality of patient portals, which may provide raw data or PDF documents without interpretive support, search functions, or timeline visualization
- Barriers related to digital literacy and technology access, which exist among older adults or caregivers who do not have reliable broadband access, modern smartphones, or familiarity with digital tools
- Inconsistent use of HL7 FHIR and United States Core Data for Interoperability (USCDI) standards, which impedes the coordination across data, provider organizations, and health information networks

Expanding the use of structured APIs will increase data availability so TEFCA payloads are transformed into FHIR-native formats. This requires certified patient-facing tools to support visualization, explanation, and navigation capabilities for harder-to-access data types. Improving health management can be achieved by using the appropriate new technology to rapidly build a foundational clinical health record for every CMS beneficiary using currently available claims data.

New technology ingests raw adjudicated or unadjudicated claims (Medicare Part A, B, and D and Medicaid claims), applies transformational data processing that extracts and encodes discrete clinical information from these claims, and builds a single, integrated, patient-centered, clinical health record for every CMS beneficiary. Since this data would be fully understood, dynamic, and reusable, CMS could use and share the record for direct care (value-based care), workflows, research, clinical trials, enrichment of Blue Button 2.0 and EHRs etc.

PC-3 Health Management, Care Navigation, or Personal Health Record Applications for Medicare Beneficiaries and Caregivers

Medicare beneficiaries and caregivers require useful applications that provide multi-channel access across diverse user needs and that are not limited to a single portal or viewing experience.

Useful applications include:

- HL7 FHIR and SMART On FHIR to support a federated ecosystem of applications, devices, and services operating over a shared data mesh to enable broad access, policy alignment, and tailored data presentation
- Powered by semantically structured, policy-award data representations and use CMS data to display care history as a longitudinal timeline, highlighting care gaps and preventive opportunities
- Offer personalized benefit tracking across Medicare, Medicaid, and supplemental plans with role-based interfaces that support both patients and authorized caregivers
- Support HL7 FHIR access with embedded logic to explain diagnoses, procedures, and coverage implications

PC-4 Features Missing from Applications Today

Most applications today lack the ability to semantically interpret CMS data across different users, which is necessary to support more effective health management. Today's applications are not able to use available claims and health data to explain care patterns, the impact of incomplete documentation, or the relationship between services and policy and care expectations. Key missing features include:

- Semantic overlays that explain events based on CMS coverage, risk adjustment, or quality guidelines
- Interactive timelines that show condition progress, procedural history, and expected follow-up services
- Cross-program benefit visualization, especially for dual-eligible individuals or patients transitioning across Medicare Advantage plans
- Role-sensitive views that adjust content and tone for patients, caregivers, advocates, and clinical support staff
- Patient-friendly "at-a-glance" views of relevant data to inform decisions or drive action

The addition of these features and capabilities would enable CMS and integrated applications and platforms to determine the following:

- What has happened to the individual? (both for historical/baseline medical relevance and for comparison to what ought to have happened)
- What is happening now (or at any specified point) to the individual ("status")? (compared to what ought to be happening)
- What is planned to happen to the individual? (compared to what ought to happen in the future)

PC-4.a Applications That Should Exist and Why They Do Not

Several high-value applications remain absent from the market due to limitations in access to structured, policy-aware CMS data. These include:

- Applications that detect unsupported diagnoses linked to risk adjustment submissions and alert the user or provider to resolve discrepancies
- Cross-program simulators that help beneficiaries forecast benefit eligibility or out-of-pocket

costs for upcoming care based on real claims and enrollment history

- Visual authorization trackers that display pending, approved, or denied requests and explain plan logic in plain language
- Preventive adherence dashboards that show whether CMS quality targets are being met and what actions are needed
- Applications with the ability to compare plans and potential total cost
- Applications with the ability to consolidate and reconcile my health data across systems and to inform systems of those conflicts (the Reverse Blue Button 2.0)
- Applications with the ability to support navigation of steps and to be informed on processes of live bill payment, preauthorization, and denials of care/claims
- Applications related to virtual first approaches, including text, secure chat, and other asynchronous communication methods. A virtual first capability can improve care while avoiding costly care channels

PC-4.b Workflows CMS is Uniquely Positioned to Offer

CMS orchestrates longitudinal, policy-aligned data workflows and has the visibility to unify healthcare histories across programs and regions. CMS is uniquely positioned to offer:

- A unified, patient-authorized timeline that integrates claims, enrollment, and quality data across Medicare Fee-for-Service, Medicare Advantage, Medicaid, and supplemental benefits
- A real-time benefit utilization view showing the status of authorizations, coverage limits, cost-sharing thresholds, and remaining benefit periods
- Preventive care tracking based on CMS quality and care management rules, with built-in prompts for follow-up
- Reasoning-enabled decision support, such as identifying when care is missing, duplicative, or inconsistent with established guidelines

These workflows can be delivered through certified APIs and SMART applications built on a semantically validated HL7 FHIR backbone. CMS can define and enforce this structure through rulemaking and implementation guidance.

PC-5 Encouraging Interest in Digital Applications

CMS can encourage broad adoption and interest through delivering digital health products that are personalized, explainable, and actionable. It is important to align applications with beneficiary needs to deliver clear and verifiable insights that derive from trusted CMS data sources. The implementation of standards, technical enablement, and incentives will encourage patient and caregiver interest in digital health products. Rapid implementation of data standards and removal of information blockage is critical. The following are needed:

- Standardization of HL7 FHIR outputs across patient-authorized APIs and requiring that these outputs be semantically enriched and policy-aligned
- Certifying applications that meet technical, semantic, and accessibility criteria, and listing them in a trusted CMS directory of approved tools

Technical enablement that accelerates the use of high-quality digital applications includes:

- Demonstrating reference applications to show how data can be used to drive navigation, close care gaps, and reduce documentation errors
- Partnering with community-based organizations, advocacy networks, and caregivers to raise awareness and provide training
- Enabling an identity management solution for patients with a single sign-on and view into their personal health record that includes their data from all their providers

Aligning incentives to desired outcomes to reduce cost and complexity, include:

- Producing HL7 FHIR outputs
- Using semantically structured data that is understandable and usable across platforms and applications and accessible by beneficiaries
- Demonstrating removal of data silos and
- Effective sharing of semantically structured data and information across entities, applications and platforms

PC-5.a CMS Role in Reviewing Digital Applications (Role, Process, Tech, Policy, Adoption)

It is important for CMS to create standards and conformance across health products that use CMS data and/or for those that are intended for Medicare beneficiaries. While CMS does not need to make clinical effectiveness judgments, technical, semantic, and policy criteria must be defined to present accurate, explainable, and benefit-aligned data for patients. Digital application reviews include:

- Data fidelity to deliver compliance with the use of HL7 FHIR and US Core Implementation Guides with semantic validation
- Alignment with CMS policy logic, including benefit eligibility rules, risk adjustment documentation requirements, and quality program expectations
- Transparency of logic so users can understand how insights or recommendations are derived
- Accessibility based on compliance with Web Content Accessibility Guidelines (WCAG) standards, multilingual support, and accommodation for cognitive or physical limitations
- Security and privacy so data is handled with proper authorization, audit logging, and role-based access controls

Recommendations to increase adoption include semantically structured data transformation and incentives and enablement.

- **Semantic-structured Data Transformation:** Provide a semantic-structured reasoning layer that operates on HL7 FHIR and reflects CMS policy logic. This transforms data fragments from all points-of-care sources (e.g., EMRs, EHRs, HIEs, Labs, Pharmacies, Claims) and many different formats (e.g., HL7, FHIR, X12, flat files) into a single narrative about the individual. This can expand available data in the Blue Button 2.0 and enable new and improved applications for health management, care navigation, and personal health records.
- **Incentives and Enablement:** Reimbursement incentives to remove silos enable sharing and increase shared data usability for enhanced health management. Technical enablement

support demonstrates the use of structured transformed data and launches public-facing campaigns to build awareness and confidence.

PC-5.b Changes for Timely Access to High-Quality CMS and Provider Generated Data

A multi-pronged strategy is needed to focus on standardization, infrastructure, and integration. These include:

- Delivering any shared data through Blue Button 2.0, TEFCA, or other channels in HL7 FHIR format with structured semantic tags
- Requiring Medicare Advantage encounter data and Medicaid service use are included in patient-authorized data feeds
- Standardizing formatting and availability of prior authorization status, appeal decisions, and referral activity
- Implementing real-time data delivery protocols across contractors and state partners to reduce lag in claims, coverage, and enrollment updates
- Providing a centralized semantic reasoning service that processes raw claims and enrollment data into structured timelines, policy validations, and navigation cues for digital applications

Each change supports the broader CMS Value Case, helping transform CMS from a data holder into a real-time, policy-aligned information provider.

PC-6 Helpful Features for Medicare Beneficiaries and Caregivers with Limited Digital Tool Experience

Accessibility must be designed into both the user interface and the data structure powering the tool. Helpful features include:

- Plain-language explanations of services, diagnoses, benefit structures, and documentation requirements
- Language support to enable non-English speaking beneficiaries and their caregivers to seamlessly review and understand their health information
- Understandable reading levels, as suggested by some State Medicaid directors who believe that instead of a traditional eighth grade reading level, a fourth grade reading level would benefit undereducated populations
- Visual timelines and condition-based navigation to help users understand how care events connect and what to expect next
- Role-based views allowing caregivers to act on behalf of patients with appropriate access levels and alerts
- Support for voice interaction, screen readers, and multimodal input for users with vision, literacy, or dexterity limitations
- Low-bandwidth functionality and offline access, especially important in rural or underserved areas
- Communication and collaboration tools for all modes which include the ability to collect and share data (including health, life, and social determinants) with the healthcare system

- Data and information collection tools with the ability to share with healthcare systems for possible inclusion into the medical record
- Simple user experience built using Human-Centered Design (HCD) principles across multiple modalities with adoption and use for all patients regardless of the payer (Medicare, Medicare Advantage, Medicaid, Children's Health Insurance Program (CHIP), Qualified Health Plans, etc.)

PC-7 CMS Collection of Real-world Data on Digital Health Products' Impact on Health Outcomes and Related Costs

The evaluation of digital health products' impact in improving health outcomes and related costs is key to measuring success and for ongoing CMS reform activities. If a tool or application shows limited or no value, it should be removed from CMS program requirements. CMS can require applications to make products' data available, such as:

- Ability to integrate measurement into existing data flows, quality frameworks, and semantic reasoning systems
- Ability to embed application usage metadata into patient-authorized API calls, with appropriate consent, and to track how often digital tools are used, and in what contexts
- Ability to compare care outcomes, quality scores, and risk adjustment completeness between users and non-users of certified digital tools
- Ability to link application use to service use patterns, such as reduced emergency visits, improved preventive service uptake, or lower denial rates for authorization

Data Access and Integration

PC-8 Health Data Available and Valuable for Patients and Caregivers

Currently, valuable clinical and claims data are available to patients and caregivers but not in a consolidated platform. Medicare claims data help patients understand billed services, providers, and dates. Summary-level coverage information is available through Blue Button 2.0 APIs and plan-specific portals. This data is often presented without interpretation or visualization. Patients benefit most when data is semantically structured, contextualized with policy and benefits, and linked to timelines and care pathways. Enriched claims data aids navigation, benefit tracking, and preventive care. Although data is available in silos, CMS is uniquely positioned to drive the change needed to increase patient engagement in healthcare.

PC-8.a Valuable Data That is Hard to Access or Use

- Person-centric data in which historical and recent relevant data are available but difficult to access because the data does not "follow" the patient due to lack of interoperability. Examples include when a patient switches from traditional Medicare to a Medicare Advantage (MA) plan or vice versa
  - Changes from traditional Medicare to a Medicare Advantage plan or vice versa
  - Switches coverage from a Qualified Health Plan (QHP) or private payer to a state Medicaid plan or vice versa

  - Switches coverage due to a job change or qualifying health/life event
- MA encounter data which are often delayed, incomplete, or not made available through APIs
- Clinical Data such as operative and encounter notes which contain critical context for understanding services delivered but are rarely included in patient-facing records
- Prior authorization requests and status updates are difficult to track and not consistently represented across systems
- Supplemental benefit use such as dental, vision, transportation, and post-discharge meal support, which is not presented in a unified or structured format
- Real-time appointment availability, provider directories, and cost estimation tools, which are especially useful for patients choosing between plans or providers
- Patient-generated data such as patient-reported outcomes or wearable device data, since these types of data have not yet been integrated into clinical records
- Documents that are traditionally shared through nationwide networks using query and retrieve type transactions, since these types of data are not semantically interpreted, are not incorporated into clinical records and require an extra step to trigger the data flow
- View-only versions of summaries or longitudinal HL7 Clinical Document Architecture (CDA) documents (finding the relevant information in these as part of the workflow is so time-consuming for providers that adoption and use has been low, leading to low impact on improving outcomes)
- Unstructured data only becomes actionable when structured using HL7 FHIR and interpreted through policy logic (without these layers, raw data offers limited value to patients or caregivers)

In addition, there are several unavailable Data Types and Obstacles for Health Data and Finding Care through patient-facing portals or digital health applications. These include diagnostic imaging and test results, clinical notes and discharge summaries, authorization status and referral tracking, and Medicaid service data (**PC-2.c**).

CMS can deliver structure and provide tools to harvest data from medical records. This will increase the value of the above items and allow CMS to improve care that is funded through its programs.

PC-8.b Specific High-Value Data Sources

Sources of data beyond traditional claims and clinical documentation can offer high value. Structured access to these datasets would expand the utility of digital health tools and promote equity in service navigation. Some of these sources and reasons for their contributing value are:

- **Social Determinants of Health (SDOH)**: These data points help contextualize patient behavior and likelihood of treatment plan adherence, so will support tailored care planning (examples include housing status, food insecurity, and transportation needs)
- **Program Eligibility Data**: These sources determine benefit pathways and help patients understand what services are accessible (examples include state Medicaid enrollment, dual eligibility status, and waiver participation)
- **Appeals and Grievance History**: Help caregivers and advocates identify patterns of denial or systemic delays

- **Community-based Service Utilization**: Links to area agencies on aging, community health workers, and wraparound support
- **Patient-Generated Health Data (PGHD)**: Current information about patient preferences, actions and decisions, wearable device data, fitness and dietary, updates to records, SDOH, and other health and life information
- **Self-assessment Data**: Provides patients with alerts, notifications, and prompts such as "how am I doing?" or "how I am doing compared to my peers?"

PC-8.c Opportunities and Challenges to Data Accessibility, Interoperability and Integration for Meaningful Use, Clinical Research, and Actionable Evidence

Opportunities include:

- Creating a single, curated health record for every beneficiary, available anywhere via wireless connectivity, that enables the patient and their caregivers to collaborate and navigate on their bespoke care pathway
- Requiring TEFCA payloads to support HL7 FHIR resource delivery, enabling semantic alignment across systems and reducing reliance on scanned documents or narrative text
- Embedding FHIR Clinical Reasoning modules into certified systems to support quality measurement and comparative effectiveness research
- Standardizing use of USCDI and US Core profiles, which provides a foundation for common semantics and structured access across vendors and payers

Challenges include:

- Inconsistent semantic labeling across sources prevents uniform analysis
- Limited IT resources and mandates to conform to canonical standards
- Limited adoption of FHIR write capabilities hinders real-time updates and bi-directional communication
- CMS's authority and data use rules and policies which preclude the collection and/or specific permission use of certain data
- Resistance to cross-platform standardization leads to partial or proprietary implementations that do not scale nationally
- Resistance to data sharing creates data gaps within the health record
- Data duplication within the health record as different organizations send same data on the same patient (e.g., medication information from primary care providers, specialists, pharmacy, refill app, payer)
- Source of truth determination as multiple and different data components for the same beneficiary need reconciliation. For example, "The state registry document indicates the patient has had an immunization, but the patient says they have not."

CMS is positioned to address the challenges mentioned through certification, reimbursement alignment, and national implementation guidance. CMS could mandate EHRs or provide a service method to deliver viable data in an accessible and interoperable manner. Similarly, CMS could provide or mandate that vendors have tools, systems, and processes so that data is not just received from Health Information Exchanges (HIEs) (and patients), but so that it is processed and

is usable in the context of patient need (or healthcare need). This includes comparison, identification of potential conflicts and errors, and means to adjudicate findings.

PC-9 Valuable CMS Data for API Developers of Patient and Caregiver Digital Products

Transition Blue Button 2.0 from static Binary Large Object (BLOB) unstructured data forms (e.g., PDFs) to discrete data elements (e.g., individual lab test results, medications, conditions, etc.) that are usable, searchable, can be repurposed, graphed, trended, etc. Additional data sources that would increase the value of Blue Button 2.0 APIs include:

- Pharmacy prescription refill data (Surescripts)
- Major reference laboratory results and reports (LabCorp, Quest Diagnostics)
- State Immunization Registries
- MA encounter data, formatted in HL7 FHIR with full diagnostic and procedural detail
- Prior authorization and referral records, including request status, approvals, denials, and required next steps
- Supplemental benefit tracking, such as dental, vision, hearing, and in-home support, especially under Special Needs Plans (SNPs)
- Plan formulary logic and coverage restrictions, linked to real-time pricing and benefit tiers
- Social risk factor screening results structured using HL7 Gravity Project standards
- Clinical notes and reports including encounter history and results

These datasets should be made available in a patient-authorized, FHIR-native format to support reasoning, navigation, and care comparison.

PC-9.a Difficulties Accessing or Utilizing Data Sources

- Lack of semantic standardization makes it difficult for developers to interpret data across plans or contractors
- Delayed availability of MA encounter data reduces its relevance for navigation or care planning
- Fragmentation of prior authorization workflows are not unified across issuers and are rarely exposed to third-party tools
- Lack of state-level Medicaid data integration, particularly for dual-eligible individuals and those in managed care, contributes to interpretive difficulties

CMS can resolve many of these issues by requiring standardized HL7 FHIR delivery across all programs and embedding semantic validation in the Blue Button 2.0 platform.

PC-9.b Suggestions to Improve Blue Button 2.0 API Experience

- Expand data elements available through APIs to include all encounter, benefit, authorization, and supplemental service data in HL7 FHIR format
- Embed semantic validation tools to consistently interpret returned data across vendors

- Support configuration of patient-specific dashboards and timelines directly from Blue Button 2.0 API feeds using open standards
- Enable more features that allow beneficiaries to interact with the information that is available by the API and/or from within the Blue Button 2.0 application itself
- Revisit the design of a patient summary for the patient using modern AI and GenAI
- Enable developer registration and sandbox testing with real-world scenarios, fostering innovation in the digital health ecosystem

PC-9.c Non-CMS Data Included in API

Non-CMS data to improve patient navigation and insight:

- Provider scheduling and availability data integrated from provider directories
- Community-based service availability such as transportation, food delivery, or in-home support managed by CBOs
- Third-party SDOH screening data shared by accountable care organizations or community networks
- Device-generated health data such as remote monitoring alerts, when structured and validated against plan goals or care gaps
- PGHD and voluntarily shared data based on a centralized location, allowing patients access to their data

These sources can be federated through SMART-enabled APIs and linked to CMS records using standard identity and consent frameworks. This framework automatically authorizes the data flow to authorized users, thereby reducing the ongoing burden of constant action by providers or patients to “share” data.

PC-10 Trusted Exchange Framework and Common Agreement™ (TEFCA™) Advancement of Patient Access to Health Information

TEFCA provides a national trust and routing framework for exchange across qualified networks. For patient access, TEFCA’s current impact remains limited due to its focus on document-based exchange formats that are not easily interpreted by patients or used in real-time navigation tools.

Where TEFCA is implemented, patients may gain access to consolidated clinical documents upon request. However, the documents are typically not semantically structured, limiting their usability in digital health applications.

PC-10.a Specific Examples

Examples of current TEFCA-supported access include:

- Patients receiving PDF copies of continuity of care documents through Qualified Health Information Network (QHIN)-connected applications
- Providers who submit documents through TEFCA-supported networks that include visit summaries and referral instructions
- EHR-connected patient portals offering cross-organization visit summaries, although not yet

in semantically structured formats suitable for analytics or explanation

These examples highlight transport success, although they do not yet reflect reasoning-ready or patient-friendly data.

PC-10.b Suggested Changes to TEFCA

Suggested changes to TEFCA include:

- Use of Federal Claims/Encounter-Based Records
  - Claims and encounter data is the most comprehensive longitudinal dataset in existence for many populations (Medicare, Medicaid, Tricare, VA, Indian Health, etc.)
  - CMS, SSA, VA, DoD, and even commercial payers have long transactional histories that EHRs and HIEs often do not capture fully
  - Many patients may not have prior clinical data in any given HIE or QHIN, but claims records exist for nearly every care episode
  - Patient matching can be dramatically improved by using longitudinal payer data as a pre-filter or enrichment layer to guide clinical queries
- Creation of a CMS/ASTP Sponsored National Claims Pilot
  - CMS (or a public-private partnership) develops a pilot that uses de-identified or limited data sets of claims to inform QHINs and HIEs where care has occurred
  - Pilot evaluates scalability, privacy compliance, and query efficiency improvements
  - Support Privacy via Minimum Necessary Data Sharing
  - No Protected health information (PHI) or clinical payload is exposed during record location phase — only existence of records and general location
  - Fully aligns with the Health Insurance Portability and Accountability Act (HIPAA) minimum necessary principles
  - Federal Agencies Become Anchor Nodes for Interoperability
  - Agencies like CMS, SSA, DoD, and VA could serve as authoritative data contributors to this service, dramatically improving coverage.
- Commercial Payer Participation Could Follow
  - After federal pilot success, commercial payers could be invited (or incentivized) to contribute encounter data to broaden private sector participation
- Creation of a Dual Participation Model for HIEs and QHINs
  - Propose policy or standards updates that allow participants to belong to both an HIE and a QHIN without forcing an exclusive vendor lock-in
  - Encourage a hybrid participation framework where QHIN participation complements, not replaces, regional HIE membership
  - Protects HIE sustainability and local care coordination advantages
- Incentivization of QHINs to Offer Inter-HIE Integration Services
  - Encourage TEFCA to provide incentives or certifications for QHINs that actively integrate

regional HIE services into their offerings

  - Creates business models for both sides to collaborate rather than compete for participants
  - Promote richer longitudinal data and better clinical decision support

- Standardization of Patient Discovery Throttling and Query Optimization Requirements
  - TEFCA should enforce technical requirements limiting unnecessary discovery queries
  - Require QHINs to apply intelligent filtering, caching, or configurable request throttling to prevent “query floods.”
  - Establish query success rate benchmarks and penalties for non-productive traffic
- Establishing a TEFCA HIE Sustainability Workgroup
  - Advocate for ASTP to sponsor a standing workgroup specifically focused on protecting the sustainability and evolution of regional HIEs in the TEFCA era
  - Provide policy, governance, and funding considerations factors in existing public investments in HIE infrastructure
- Develop QHIN-to-QHIN Notification Standards for Non-Matches
  - Create standardized QHIN-level feedback loops that allow more efficient handling of non-match scenarios
  - Enables QHINs to notify originating entities when a patient has no data in a target network — reducing redundant queries
  - Supports better user experience and analytics
- Request CMS and ASTP to tie future TEFCA funding models to outcomes, not just participation
  - Reward networks that produce measurable improvements in cross-network patient matching, duplicate test reductions, avoidable admissions, etc.

PC-10.c Use Cases with Significant Impact If Implemented Through TEFCA

The following are use cases with significant impact implemented through TEFCA:

- Real-Time Care Coordination/Admission-Discharge-Transfer (ADT) Event Notifications
  - Current TEFCA lacks mature support for real-time ADT data sharing across QHIN boundaries
  - Nationwide, real-time event notification would dramatically improve care transitions, post-acute care planning, preventable readmissions, and emergency visit coordination
- Longitudinal SDOH Data Exchange
  - TEFCA is largely silent on how non-clinical data (housing, food insecurity, transportation, utilities, social services) could be incorporated
  - Federal programs (CMS AHEAD, Medicaid waivers, etc.) require full patient context for risk adjustment and care planning
  - TEFCA could incorporate: SDOH interoperability standards (Gravity Project), Community-Based Organization (CBO) participation models, and Consent models for non-clinical data sharing

- Payer Claims Data Exchange (Longitudinal Record Aggregation)
  - Current TEFCA design favors EHR-based document exchange, but payer data holds critical longitudinal gaps
  - CMS, MA, Medicaid Managed Care Organizations (MCO), and commercial plans could provide complete historical claims data, prior authorization data, and prescription adherence history
  - TEFCA could extend to integrate payer-to-provider clinical enrichment services
- National Provider Directory with Endpoint Management
  - TEFCA participants still struggle with fragmented, inaccurate provider directories
  - A national provider directory, maintained as part of TEFCA governance, could improve endpoint discovery, reduce failed queries, and support secure routing for referrals, prior authorizations, care management
- Increased Patient-Centered Access and Data Portability
  - TEFCA is still very provider-vendor-centric; patient empowerment remains weak.
  - High-value expansion areas include patient-controlled longitudinal record aggregation across QHINs, portable personal health record services, and API-based patient app integration (beyond simple FHIR access)
  - This aligns with the 21st Century Cures Act intent but needs TEFCA support and mandatory QHIN participant responses
- Clinical Quality Measurement / Population Health Reporting
  - TEFCA could facilitate cross-network clinical quality data aggregation including support CMS quality programs (Merit-based Incentive Payment System (MIPS), accountable care organizations (ACO) REACH, Stars Ratings, Medicaid waivers) and reduce redundant chart pulls and manual abstraction
  - This could position TEFCA as the backbone for nationwide clinical quality benchmarking
  - Identity Resolution and Master Patient Index Expansion
  - TEFCA lacks robust nationwide patient identity management
  - This continues to cause low patient match rates, query failures and non-responsiveness, and incomplete record location
  - TEFCA could incorporate federated identity resolution services by leveraging Federal cross-agency identity (CMS, VA, SSA, HIS, CDC, NIH, IRS), patient-directed identity verification, probabilistic and AI-based matching algorithms, and use of Identity Proofing solutions like CLEAR, Login.gov ID.me, etc.

PC-10.d Standards Working to Advance Access and Existing Exchange Purposes

- HL7 FHIR R4 and US Core Implementation Guides
- OAuth 2.0 and OpenID Connect for secure access for authorization and authentication
- IAL-2 and Authenticator Assurance Level 2 (AAL2) standards
- SMART On FHIR for patient- and provider-facing applications using trusted IAL-2 compliant solutions such as CLEAR

- Observational Medical Outcomes Partnership (OMOP)

PC-10.e Standards Not Widely Used That Can Improve Data Access and Integration

CMS can promote adoption through procurement policy and rulemaking. Some standards that hold promise but are not yet widely implemented include:

- HL7 Gravity Project SDOH profiles
- FHIR Clinical Reasoning and clinical decision support (CDS) Hooks for embedding guidance into care delivery
- Bulk FHIR access for high-volume, multi-source data integration

PC-10.f and TD-6.b TEFCA Redundant Standards, Protocols, or Channels That Should be Consolidated

Redundant use of document-based protocols (such as Integrating the Healthcare Enterprise [IHE] XCA, XDR, and Direct Messaging) should be phased out for patient-facing exchange. These formats limit semantic interpretation, cannot power real-time insights, and add friction to multi-application ecosystems. The use of FHIR APIs for all new interoperability functions should be encouraged.

PC-10.g, TD-6, PR-6 TEFCA Alternatives for Achieving Widespread Patient Access to Health Information

FHIR-based APIs authorized under the 21st Century Cures Act are already in place at many provider organizations and health plans. These interfaces offer real-time, structured access to clinical and claims data. When enhanced with reasoning logic and visual tools, these interfaces can offer broader utility than document-based exchange. CMS can advance interoperability by integrating these standards with TEFCA, not replacing them.

Direct patient access via certified EHR FHIR APIs remains crucial, especially if enhanced by our electronic health information (EHI) export recommendations. TEFCA's unique value for querying unknown data holders will only be realized if it fully incorporates patient-centric reforms. Otherwise, direct-to-EHR API access will remain the preferred, more trustworthy pathway for patients.

CMS would benefit by moving to fewer standards and frameworks focused on helping improve care delivery. Focusing on data availability and accessibility is key. This will help deliver data quality and the ability to use automation (to include AI) to validate the data. The standard should evolve and be aligned with other data exchange efforts across all CMS programs.

For providers, two examples of where TEFCA has provided value is the increase in cross-network data sharing allowing providers to access data across hospital systems using different ER vendor solutions and the increase in using TEFCA connected QHINs to meet the mandated requirements of public health reporting.

PC-11 HIEs Currently Helping Advance Patient Access to Health Information

HIEs contribute to patient access by serving as intermediaries that consolidate clinical data from multiple sources using established networks. They make data available to authorized users, including patients and their designated proxies. Some HIEs offer portals or enable data sharing with third-party applications that support care coordination and preventive tracking.

However, many HIEs remain focused on provider-to-provider exchange and many lack standardized FHIR APIs for patient access. The value of HIEs increases significantly when they enable structured, semantically tagged access to longitudinal records across institutions, plans, and service types.

HIMSS defines interoperability as "the ability of different information systems, devices and applications (systems) to access, exchange, integrate and cooperatively use data in a coordinated manner, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize the health of individuals and populations globally". HIEs can help advance patient access by 1) being part of data accessible via Blue Button 2.0 and 2) supporting the ability to compare and deconflict data on a patient from various systems.

PC-11.a Valuable, Available, and Accurate Data

HIEs have been helpful as relationship and policy builders within their state and regional population of physicians and healthcare organizations and setting up connectivity among the entities. Technologically, they have worked hard but need improvement in the following areas:

- **Data Duplication**: Same data sourced from different venues (e.g., medications from pharmacy, primary care physician, specialist, ED, refill applications, etc.) repeat within the record – overfilling it with redundant data and frustrating providers looking for the right data.
- **Data Sequencing**: A single event such as a laboratory order has multiple associated activities (e.g., order, accession, preliminary result, final result, pathology report, EOB, etc.) and each activity's data may come into the health record at a different time and in a different order, delivering disorganized and out-of-order stacking of multiple transactions of the same event. This requires the user to search through the record to find the most relevant event data. Algorithms and/or rules attempting to remedy this issue have repeatedly failed.
- **Naming Convention**: Each entity may have a different naming convention for a test or procedure (e.g., chest x-ray, XR chest, CXR, chest radiograph, etc.) equating to repetitive posting of the same test multiple times.
- **Tracking and scoring success**: Collect data on the impact and value of the HIE using a goal setting or performance measurement framework. This could include measuring: improved care coordination, reduction of ordering of duplicate images and use of the HIE. Without this data, the value of the HIE is not fully understood.

Data shared through HIEs are valuable when it includes structured encounter data, lab results, and discharge summaries. Availability and accuracy, however, vary widely by region and participant. Some HIEs offer near-real-time feeds with strong data quality, while others rely on delayed or limited submissions. The absence of semantic structure in many HIE datasets reduces their interpretability and usefulness for patients. Data accuracy improves when HIEs implement HL7 FHIR standards and validate content against national vocabularies and CMS program logic.

PC-11.b Suggested Changes for HIEs

HIEs changes for a more relevant and interoperable nationwide digital health ecosystem include:

- Primary interface adoption of HL7 FHIR APIs for both provider and patient-facing services
- Application of semantic tagging and validation against CMS-approved rule sets for consistent interpretation
- Participation in TEFCA under shared governance, while offering value-added services for clinical reasoning, alerting, and patient education
- Support of identity harmonization across Medicare, Medicaid, and commercial identifiers, enabling unified patient records

PC-11.c High-Performing HIE Models to be Propagated Across Markets

Accenture operates these high-performing HIEs:

- Alabama One Health Record® (ALOHR) was one of the first HIEs to help hospitals comply with 21st Century Cures Act and also offers real-time alerts and combines clinical and claims data on behalf of beneficiaries. ALOHR is a participant in eHealth Exchange's Qualified Health Information Network (QHIN) under TEFCA. ALOHR offers various alerts, notifications and reporting services. They are committed to participation in various national programs (VA, SHIEC-PCDH, eHX).
- Pennsylvania Patient & Provider Network (P3N) is fully integrated with all five Health Information Organizations (HIOs) within the state of Pennsylvania, as well as the PA Department of Corrections, the Office of Mental Health and Substance Abuse (OMHSAS) EHR, and the Office of Developmental Programs (ODP) to allow real-time notifications for State Agencies and Case Managers coordination of care. Additionally, the P3N is connected to the Delaware Health Information Network (DHIN), and CRISP Shared Services ADT services to facilitate broader coordination of care across the Eastern Seaboard.

Other Examples of High-Performing HIE Models include:

- CRISP (Maryland/Washington DC region) offers real-time hospital encounter alerts and structured patient summary reports and connects to other HIEs for more robust data sharing
- Manifest MedEx (California) combines claims, encounters, and social determinant data and provides predictive analytics to care teams
- NC HealthConnex (North Carolina) has integrated multiple EHRs and state Medicaid data with community health data to support longitudinal care

High-performing HIE models offer services such as:

- Consistent data ingestion from a variety of data clinical and claims data sources with the ability to parse data and generate a structured patient summary report
- Support for a variety of use cases and users including patients, providers, care teams, and public health agencies
- Expanded data to include SDOH and patient-generated data
- FHIR end points that provide meaningful curated data to provider and patient applications
- Real-time notifications with subscription services

- Provider directory services

PC-11.d Ongoing Role of HIEs Facilitating Data Exchange and Frameworks

HIEs can influence regional conveners with trusted local governance. While TEFCA standardizes national trust and routing and vendor networks scale technical connectivity, HIEs provide value through:

- Accessing data through local regional connectivity that transfer complete data sets on behalf of patients
- Data curation and aggregation across local and state programs
- Real-time public health surveillance and alerts
- Support for cross-sector partnerships involving payers, providers, and social services

HIEs should transition toward FHIR-native operations to remain aligned with national exchange standards and serve as a bridge between TEFCA infrastructure and local health priorities.

PC-12 Valuable Operational Health Data Use Cases for Efficient Care Navigation or Barriers to Competition Among Providers

These use cases support informed decision-making, promote competition on value, reduce friction in scheduling, and benefit navigation:

- Real-time access to care gaps and service history, allowing patients to avoid duplicative tests and to request timely follow-up
- Benefit simulation and cost projection, based on historical claims and current plan enrollment
- Unified authorization and referral tracking, especially across multi-specialty or cross-plan workflows
- Structured quality benchmarking, showing how provider performance aligns with national or regional targets, presented in patient-friendly language

PC-12.a Examples May Include the Following:

- Binding cost estimates for pre-defined periods
- Viewing provider schedule availability
- Using third-party applications for appointment management
- Accessing patient-facing quality metrics
- Finding the right provider for specific healthcare needs

CMS can enable these high priority use cases by:

- Making provider directories include real-time scheduling metadata and have are accessible via HL7 FHIR APIs
- Defining FHIR profiles for cost estimation and linking them to plan-specific benefit data and fee schedules
- Supporting patient-authorized applications that can aggregate care quality metrics and

provider ratings from trusted sources

- Facilitating third-party integration through Blue Button 2.0 and TEFCA-compatible endpoints with appropriate provenance and access controls

PC-12.b Possible Use Cases Today

- Viewing clinical information, derived from historical claims data, in an understandable format, externalized through the Blue Button 2.0 application
- Viewing visit history and clinical conditions for every beneficiary in Blue Button 2.0
- Viewing near real-time updates to the beneficiary's health record from transformed claims processed in the CMS ecosystem in Blue Button 2.0
- Aggregating medication history and preventive service records using SMART On FHIR
- Sharing data with authorized caregivers or third-party applications using OAuth 2.0 consent frameworks

These functions are limited by scope and semantic alignment but are available within certified applications.

PC-12.c Use Cases in the Near Future

- Inclusion of laboratory test results in each beneficiary's record
- Inclusion of pathological and imaging narrative reports in each beneficiary's record
- Application of rules that can trigger time-of-care alerts and notifications to the end users
- Structured benefit tracking across Medicare and Medicaid programs
- Authorization status tracking with real-time updates
- Quality comparison dashboards personalized by condition, age, and plan type
- Timeline-based care visualization using semantically enriched data from TEFCA and Blue Button 2.0

These features require unified identity resolution, HL7 FHIR adoption across networks, and a reasoning layer that reflects CMS policy logic.

PC-12.d Valuable but Hard to Achieve

Highly valuable but challenging goals include:

- Real-time integration of out-of-network service data across payer systems
- Dynamic provider recommendations based on availability, cost, quality, and patient preferences
- Bi-directional care planning tools that allow patients, providers, and payers to co-create treatment timelines with embedded benefit logic
- Federated analytics tools that can compute outcomes, cost trajectories, and social risk impact

These require not only technical interoperability, but also governance innovation, trust

frameworks, and sustainable business models.

Information Blocking and Digital Identity

PC-13, PR-14, PA-7 Encouraging Patients, Caregivers, Providers and Payers to Submit Information Blocking Complaints to ASTP/ONC's Portal

CMS can encourage reporting by embedding a complaint function within patient-facing and provider-facing applications, such as the Medicare portal and Blue Button 2.0 tools. This could take the form of a simplified one-click interface on which users encountering missing or withheld information are prompted to "Report a data access issue" with prefilled context.

The impact of increased reporting would be generally positive, provided the process includes triage and clarification. Elevated complaint volumes would signal systemic barriers and technology design flaws. CMS can use this as input to modify certification, procurement, and incentive mechanisms. Increased visibility into data exchange issues would support a culture of transparency, especially when aligned with TEFCA's trust frameworks. Data exchange would improve over time, especially if vendors receive guidance on how to correct identified violations.

CMS could create a single API to support this with data coming directly to CMS. There could be a requirement in CMS programs that every patient portal and other CMS-approved health IT tool has the widget to use this feature accessible from the home page. This visible and easy to access feature would encourage users to report concerns. If implemented correctly it could also facilitate the person reporting providing very specific use on what may or may not have occurred.

CMS should consider additional incentives for receipt of payer-to-payer data exchange, specifically checking for non-responsiveness to requests for information. Payers actively engaged in ACO models and their care teams working to compile a longitudinal record for a participant should begin to track, measure, and monitor requests for information including responsiveness, non-responsiveness, and quality of the information provided (structured, unstructured, summary information and/or comprehensive information). CMS should consider a new IT certification program for payers more directly involved in CMS programs such as MA and value-based care (VBC) models. As part of this program, CMS can include a requirement for care teams to regularly submit complaints of information access blocking to CMS.

PC-14, PR-9.b and TD-3.a Digital Identity Credentials Using CLEAR As the Recommended NIST 800-63-3 IAL2/AAL2 Credentialing Service Provider (CSP)

We recommend enabling a federated identity management solution for patients with a single sign-on and view of their personal health record that includes data from all their providers and payers.

CLEAR and Accenture Federal Services have successfully deployed a product in-market implemented in production. Without an IAL-2 solution such as CLEAR, beneficiaries are required to complete in-person or telehealth-based identity verification. While secure, these processes presented accessibility barriers, particularly for rural, elderly, or transportation-limited individuals.

In practice, IAL2 enables scalable, interoperable identity frameworks—so that, as an example, a Medicare beneficiary can access multiple services (from account recovery to Medicare Blue Button to digital health tools) using the same, verified identity. This reduces the need for multiple logins and unlocks better experiences across the ecosystem.

With over 15 years of experience simplifying and securing access, CLEAR offers a scalable, privacy-centric identity solution for the healthcare industry. Trusted in zero-fail environments, CLEAR is designed to optimize the end-user experience while maintaining the highest security and compliance.

CLEAR brings consumer-grade identity experiences to healthcare to improve access, reduce administrative burden, and strengthen security. They are trusted by national healthcare platforms like Epic (with CLEAR "Under Construction" in Epic Toolbox and powering live Vendor Services integrations), Surescripts and InterSystems. CLEAR reduces operational costs and prevents fraud by replacing legacy systems, vulnerable knowledge-based authentication and manual verification with high-fidelity biometric verification.

PC-14.a and PR-10.a Challenges for Patients/Caregivers/Providers to Use Digital Identity Credentials

The following barriers create friction at the first point of engagement during the sign-up process. Without clear pathways to credential enrollment, many patients abandon the process, directly impacting providers and their ability to engage with their patients.

- Complexity and inconsistency across CSP platforms
- Confusion about credential reuse across applications
- Limited awareness among beneficiaries of the purpose and value of secure credentials
- Access issues for individuals without mobile devices or government-issued IDs
- Trust with setting up an account with the federal government and how that information may be used

PC-14.b, PC-14.d, TD-2, and TD-3.b Benefits to Patients/Caregivers for Wide Use of Digital Identity Credentials and Impact of Cybersecurity and Data Exchange

CLEAR is an example of an identity platform that is certified to meet NIST 800-63-3 Identity Assurance Level 2 (IAL2) requirements. CLEAR's integration into third-party mobile application allows beneficiaries to complete identity verification using a mobile device, eliminating the need for in-person appointments or real-time staff availability. The identity proofing process leverages biometric verification and document validation, offering a seamless and secure user experience.

The solution allows beneficiaries to access and control their health data securely and conveniently using a tested and secure standard. Simultaneously, healthcare organizations share the burden of onboarding users across the network so that there is no need to re-enroll a user every time they move from one service to another, reducing overall cost, user friction, and increasing operational efficiency.

Expected outcomes to cybersecurity and data exchange include:

- **Expanded Access**: CLEAR's digital-first model provides a convenient alternative for beneficiaries who are unable or unwilling to participate in traditional identity verification pathways
- **Cost Efficiency**: Automated identity proofing reduces administrative overhead and reduces staffing demands associated with manual verifications
- **Standards Compliance**: The solution aligns with NIST IAL2 guidelines, meeting federal

expectations for identity assurance and identity orchestration in healthcare data exchange

- **Equity**: By removing access barriers, the solution supports broader goals of improving digital equity in healthcare delivery
- **Security and Privacy**: CLEAR is built to protect personal information and keep users in control — allowing users to control what personal information is shared, while maintaining high security standards within the industry, and with NIST and DHS. CLEAR never shares data without explicit user consent. This protects sensitive information and mitigates risks like identity theft.

Wide adoption would provide:

- Seamless access to consolidated health records across payer and provider networks
- Reduced re-authentication burden and credential fatigue using a reusable identity
- Greater confidence in digital health application security
- Reduced cost for identity proofing and cost sharing across the network of providers
- Improve trust across the ecosystem by using a well-known IAL-2 solution such as CLEAR
- Improved patient matching, reduction in duplicates and increased longitudinal data accuracy

This aligns with the policy goals of TEFCA and the 21st Century Cures Act. Wide use of high-assurance digital identity is key to simplifying and securing patient access. However, identity credentials alone are insufficient without robust, bound authorization credentials that specify what data an identified user is permitted to access and for what purpose.

PC-14.c Potential Downsides of Digital Identity Credentials

- Exclusion of underserved populations due to technological or documentation gaps
- Concerns around surveillance, privacy, and trust if CSPs are not adequately transparent
- Credential fatigue if multiple systems require separate verifications without coordination

Mitigation strategies include federated ID reuse, simplified enrollment, and community-based outreach activities.

PC-14.e Role of CMS/Payers, Providers, and App Developers in Driving Adoption

- Standardization of digital identity integration across its platforms and subsidize trusted enrollment pathways for underserved populations
- Payer alignment of enrollment processes with CMS credential frameworks and streamline credential reuse across digital services
- Credential enrollment offered by providers during in-person care episodes and educating patients on its value
- Implementation of standards-compliant login flows and avoidance of closed ecosystems that inhibit credential reuse by application developers

This multiparty engagement delivers scale, equity, and consistent user experience.

PC-14.f CMS Role in Encouraging Digital Identity Credentials

- CMS is well-positioned to normalize and simplify digital identity adoption at a national scale including the launch of a targeted awareness campaign
- Incentivize credential acquisition through benefit-linked functionality, such as access to full longitudinal records or enhanced care planning tools
- Provide grant funding for community health organizations to assist patients in identity proofing
- Pre-integrate IAL-2 compliant solutions such as CLEAR with all CMS-facing digital products and MA tools
- Provide patients with the option to use third-party credentials and make informed choices about the credentials they wish to use

Providers

PR-1 Encouraging Provider Use of Approved Digital Health Products for Patients, in Rural Areas

We recommend CMS engage in a proactive and multi-faceted approach to encourage providers to use approved digital health products. To further accelerate the effort in rural areas, we recommend that CMS invest in a targeted education, communications and marketing campaign given that approximately 60 million people including millions of Medicare and Medicaid beneficiaries live in rural areas.

PR-1.a Current Obstacles

For telehealth, the limited ability to reimburse virtual and asynchronous health support is a major obstacle. Some obstacles for expanded use of approved digital applications, especially in rural areas include:

- Broadband access
- Limitations on data availability, interoperability, and usability
- Patient acceptance and trust
- Security concerns
- Changes in management and time required to learn new technologies
- “First, do no harm” culture can create resistance to change
- Skepticism about past changes that have increased workload and perception of decreased productivity
- Limited IT resources within provider practices to comply with ongoing requirements

PR-1.b Information Providers Share with Patients Through Digital Products

- Authorized users (including patients) have full access to their health record data
- Access to records by other, non-healthcare professional caregivers such as spouses
- In some cases, the Custodian may choose to delay the release of information for patient

viewing (e.g., 24/48 hrs.) of certain sensitive reports or results to provide enough time for the physician to contact the individual with insight into the data

- Establish data restrictions by the individuals (beneficiaries) themselves or by the data Custodian, (an entity designated to act on the individual's behalf)
- Physician access to an individual's record is usually based on his/her relationship with the individual, but the individual should be able to tailor this access for a specific clinician

Providers and their staff can further promote the use of tools by expressing their confidence in the tool, demonstrating how to use it, highlighting the benefits it offers to the patient, and explaining how the information gathered will be utilized in clinical care to support the patient's well-being.

PR-1.c Provider Responsibilities in Recommending the Digital Product Use

- Testing, compliance, and studies conducted by an unaffiliated third-party authority
- Limits, intended use, and security of tools they recommend
- How to integrate the use of digital tools or data into the care of the patient
- Alignment with an organization that trains the patient on product and delivers ongoing support

PR-2 Development, Deployment, or Utilization Obstacles and Mitigations

The past 15 years of EHR adoption have generated more digitized healthcare data than ever before; however, more data has not resulted in better outcomes. There is no single online location where physicians, caregivers, and patients can see their health information. The presence of silos of data in various formats is a significant barrier to success. Data restrictions limit the benefit of digital tools. New technologies are available that can transform raw or structured data into useful and usable patient information. CMS can incentivize stakeholders with patient data to share by pointing out the benefits of delivered information being transformed into an understandable and reusable format.

PR-4 Changes/ Improvements to Standards or Policies Needed for Patients' Third-Party Digital Products

CMS can make a truly open API without an information blocker for specific use cases. This starts with access to patient health data and demographics as foundation. It must include specific items such as:

- Writes into the EHR with approval by clinical team using an agreed upon workflow.
- Progress note insertion and signing and billing/encounter information to the EHR.
- Access to information on other data as detailed in specific workflows including appointment scheduling data.

Data Exchange

PR-5 FHIR APIs and Capabilities Already Supported/Utilized

New technology for data treatment processes are now available to ingest data in any format or load, curate and transform the fragmented components and export this information into fully understood information via APIs in various fit-for-use outputs such as direct patient care, research, clinical trials, and more. The data provided by this data treatment process can improve the usability and health benefit for CMS and across platforms and providers.

PR-5.a to PR-5.i FHIR APIs Supported

We support a variety of provider organizations who have implemented FHIR APIs both directly and through an intermediary. For example, many of the hospitals work both with their EHR vendor and regional HIE for data sharing purposes. Many are directly sharing with trusted parties using modern API specifications.

FHIR API / Capability	Transaction Model	Use Case	Query Type	Constraints
Patient Access API	RESTful FHIR (R4)	Patient record access via third-party apps	Individual, some bulk	Varies by EHR; SMART on FHIR token enforcement
Provider Directory API	RESTful FHIR	Provider network publication and lookups	Bulk, individual	Data quality, credentialing source variability
Payer-to-Payer Data Exchange API	FHIR Bulk Data ($export/$import)	Patient history transfer when changing insurers	Bulk	Patient matching inconsistency, varied authorization models
Clinical Data Exchange (e.g. DEQM, PDex)	RESTful FHIR, CDS Hooks in some cases	Quality reporting, risk adjustment, payer-driven authorization	Individual, batch	Terminology normalization often needed
Bulk Data Export ($export)	FHIR Bulk Data (Flat FHIR, NDJSON)	Research, population health, payer reporting, migrations	Bulk	Performance tuning, timeouts, async job handling
SMART on FHIR App Integration	OAuth2 via FHIR endpoints	Integration of mobile/web apps with EHR	Individual	Requires app registration, token scope controls
Prior Authorization Support (e.g. Da Vinci PAS)	FHIR + X12 EDI hybrid	Automated prior auth workflows between provider and payer	Individual	Complex orchestration; intermediary layer often required
Scheduling API (e.g. Argonaut)	RESTful FHIR (Appointment, Schedule)	Scheduling via patient-facing or partner apps	Individual	Incomplete scheduling granularity; custom slot mapping needed

Encounter and Claims Data (e.g. CARIN BB)	RESTful FHIR (Claim, EOB)	Transparency tools, cost estimation, payer integrations	Individual, bulk	Adjudication detail may be partial; payer-specific constraints
Document Reference and Clinical Notes	RESTful FHIR (DocumentReference, Binary)	Sharing clinical notes, imaging reports, scanned docs	Individual, some bulk	Handling of PDFs and binary formats needs additional infrastructure support

PR-7 Strategies to Implement and to Support Providers in High-Quality, Timely, and Comprehensive Healthcare Data for Interoperability in Digital Product Ecosystem

Enablers for providers to share data for interoperability in the digital ecosystem include the combination of incentives and requirements for certified EHRs to provide data sharing by design and by desire without any blocking; certified EHRs to provide tools and services in place to provide data received in a completed, compared, and variable manner that is fit to the user role and workflow; and participation in the data sharing ecosystem by applying new technologies to ingest and transform data in varied formats and make that available to providers, and other authorized interoperability entities.

PR-8, PR-8.a, PR-8.b, Simplifying Clinical Quality Data Responsibilities of Providers and Benefits

CMS can simplify what and how clinical quality metrics are in place. Use of bulk FHIR for automated submissions help provider organizations. This can be supported by AI and automated data extraction so data measures are checked and validated for quality and completeness of submissions. This includes the structure and process to adapt to evolving clinical quality metrics evolution resulting from technology.

Bulk delivery of targeted patient care data in a standardized form allows CMS to calculate quality measures for its beneficiaries allowing the analysis, aggregation, and comparing quality across. Quality reporting should not be a task added to the providers' workload. A well-designed system makes the review and determination of care quality patient-specific and calculated in real-time as data is added to a patient's record.

PR-8.c Requirements for Data Registries to Support Digital Quality Measurement

Data supporting quality initiatives should be carefully curated, fully understood, and void of duplicated data and in context to the patient and the initiative. While data quality is critical, this question highlights why registry data should not be considered different from patient data. Data is the core asset. They are critical to care quality, efficient care delivery, decision support, and enabling the value of AI.

If this does not occur, real-time use of data to inform clinicians will not be possible. This does not reduce the value or use of registries, but delivers key and relevant data for patients, population health, disease, and registry cohorts. Additionally, increasing EHRs' required tools should result in simplified and automated reporting.

Digital Identity

PR-9 Encouraging Providers to Accept Digital Identity Credentials

The fragmented landscape of healthcare authentication creates barriers for stakeholders and patients to move healthcare toward the Quadruple Aim. The path forward does not necessarily involve abandoning proprietary logins but should require all certified systems to allow users to choose their preferred login option. Vendors may initially receive financial incentives, with an eventual transition to financial disincentives with lower payments for Medicaid and Medicare if non-compliant. Patient engagement is critical to better health at lower cost, and allowing user-chosen login options will increase ease of engagement, particularly among demographic groups previously noted. This implementation should come with clear standards, guidelines, and technical support.

PR-9.a Accelerating the Transition to Single Set of Trusted Digital Identity Credentials

An accelerated transition requires the implementation of access to alternatives with clear standards, guidelines, and technical support. This includes planned support for the inevitable evolution of standards. To accelerate adoption, it will be essential to market and educate healthcare providers and patients on the value of a trusted digital identity. This includes simpler access and improved security.

PR-10.d Impact Mandatory Credentials Have on Nationwide Provider Directory

Mandatory credentials can improve accuracy and public trust in a nationwide provider directory. The nationwide provider directory provides health management benefits to beneficiaries and caregivers. Considerations and benefits:

- Mandatory data fields on providers made available through CMS
- Frequency of update and associated requirements for current and reliable information
- Support for providers to reduce burden of data collection and update
- Mitigate risks challenges of “ghost networks” with unreachable providers
- Support referrals and care delivery for beneficiaries

Technology Vendors, Data Providers, and Networks

Technology vendors, data providers, and networks play a critical role in advancing digital applications for health management and care navigation. CMS’s efforts on increasing data availability and value through components and requirements include:

- Providing a data transformation layer
- Establishing required use of HL7 FHIR outputs
- Establishing requirements for universal IDs
- Enabling technology and public awareness efforts
- Aligning incentives with application value and use
- Encouraging use of applications by developing web-based applications

- Sharing data across platforms and organizations
- Complying with CMS application certification requirements
- Facilitating flexible user experience and value to the provider aligned with workflows
- Augmenting use of digital applications for telehealth to support rural areas
- Aligning incentives and payments for healthcare delivery and health support delivered virtually and/or asynchronously
- Implementing adjustments (e.g., for Evaluation and Management codes) to support asynchronous and virtual engagements to reduce administrative burden and improve coding accuracy
- Support asynchronous encounters and hybrid visits by adjusting current rules about timing during the calendar day
- Recognizing and reimbursing services provided by members of healthcare teams aiding patients in rural and underserved areas

TD-1 Short and Long-Term Steps to Stimulate Developer Interest in Building Digital Health Products for Medicare Beneficiaries and Caregivers

Healthcare information technology (HIT) is a sought-after sector for both startups and established companies. However, it is complex, requiring an understanding of regulations, workflows, and various clinical and administrative facets. Despite the increase in digitized healthcare data and newly developed digital health products since the Health Information Technology for Economic and Clinical Health (HITECH) Act, outcomes have not improved due to barriers such as:

- Lack of interoperability and insufficient data sharing
- Redundant and misunderstood data fragments
- Insufficient adoption of many digital health products

Short Term (< 2 years) Recommendations:

- Use certified electronic health record (EHR) technology (CEHRT) program to enhance existing interoperability efforts through expansion of APIs
- Provide additional guidance requiring the use of FHIR for the Full EHI Export requirement
- CMS to fund efforts that encourage patient mediated data exchange to combine clinical and claims data into a usable format with new technologies

Longer Term (2+ years) Recommendations:

- Continued use of CEHRT program to enhance interoperability efforts
- Inclusion of requirements in CMS programs, conditions of participation and in VBC arrangements that engage developers and encourage modern features

TD-2 Regarding CMS Data, to Stimulate Developer Interest

CMS has claims data (and more clinical data) on 68.5M beneficiaries that with the latest technology, can be the foundation of health records for all Medicare beneficiaries and, in partnership with states, could extend to Medicaid and CHIP. Every HIT developer is reliant on the

data they receive. CMS can engage the interest of a variety of stakeholders if it can produce empirically true and fully understood data that developers need to produce a successful product.

TD-2.a and PA-2 Additional Valuable Data Types Through CMS APIs

The types of data that patient care delivers include:

- Laboratory results, imaging reports, immunizations, medications, care notes, patient entered data, vital signs, home care, SDOH, and more
- Most digitized data sources should be available through a CMS API at least daily
- Expand detailed information for medications such as medication fill data. This information can help providers target follow-ups and improve medication management
- SDOH data on housing, food security, transportation, and life and preference data to support holistic care applications
- Authorized caregiver data to enable applications for family support
- Encounter data that Medicare Advantage plans report to CMS today. CMS can encourage these participating payers to use APIs by requiring MA plans to use APIs and FHIR

TD-2.b and TD-12 Data Sources Alongside Data Available Through Blue Button 2.0 API

Of the data sources listed in Question TD-2.a, some of the most valuable and available include laboratory results, prescriptions/medications, and immunizations as well as:

- EHR Data including structured data and notes
- Patient Generated Health Data (PGHD)
- Community and open-source data sets to assist with Social Determinants of Health (SDoH)
- Real-time data from wearable/device data like glucose monitors or fitness trackers for chronic disease management
- Other healthcare data on the patient (from the payer) to complete patient view including their health journey and their needs

CMS should endorse non-CMS sources to broaden data access, while maintaining a single standard for interoperability, security to include HIPAA compliance, reliability and traceability. There should be metrics for speed of exchange, compliance, completeness, and user satisfaction.

TD-2.c Obstacles Preventing Accessing Data Sources

Laboratories such as LabCorp and Quest hold a large percentage of test results. PBMs and prescription intermediaries, such as Surescripts, hold a large amount of medication information, and most states have immunization registries. Relationships and integration strategies would be required to source this data.

Policy and regulations may need to be put in place to support the distribution of this information. Many organizations lack dedicated data analytics staff to process flat files or claims data dumps, creating a lack of standardized and digestible data.

TD-2.d APIs CMS and ASTP/ONC to Consider Prioritizing

In addition to the many existing standard APIs defined today in various incentive programs and use cases for FHIR mentioned throughout this RFI response, we recommend CMS and ASTP consider prioritizing the following four APIs:

- Patient Summary API for third party applications that include expanded data elements
- Provider Directory APIs for finding and connecting with providers across systems
- Prior Authorization APIs to streamline approvals and reduce delays to include ability to query and understand authorization requirements and denials
- Encounter API for Medicare Advantage reporting to CMS

TD-3.c Mandatory Use of OpenID Connect Identity Protocol Impact

In addition to IAL-2, OAuth 2.0 and OpenID Connect are recommended for secure access. These standards are complementary to one another and are all recommended. The impact of making it mandatory would support the recommendation for federated identify management.

Technical Standards and Certification

TD-4 Encouraging Use of Open, Standards-Based, Publicly Available APIs Over Proprietary APIs

CMS can continue to use levers and incentive programs such as the CEHRT program, hospital conditions of participation, and require the use of those same APIs in Alternative Payment Model (APM) models to encourage and require the use of open, standards-based APIs. CMS can continue to partner with SDOs such as HL7 to publish implementation guides for program-specific APIs to deliver feedback from industry. CMS can offer through existing programs such as the CMS Electronic Submission of Medical Documentation (ESMD) additional methods of submitting data using both API standards for transport as well as FHIR for the payload.

TD-5 Nationwide Provider Directory of FHIR Endpoints and Improved Access to Health Information

Nationwide provider directory benefits include:

- Ability for patients to easily search for specialists
- Provider-to-provider exchange facilitated by providers
- Payers, ACO participants, and care teams can efficiently locate and coordinate care with a wider network of specialists

CMS and the Office of the National Coordinator for Health Information Technology (ONC) are uniquely positioned to facilitate the development and implementation of a nationwide provider directory. To deliver adoption and use the following should be considered:

- Data should be made available through easy to access, no cost, FHIR endpoints
- CMS should align to other provider systems such as National Plan and Provider Enumeration System (NPPES) and Provider Enrollment, Chain, and Ownership System (PECOS) to deliver

continuous accuracy and alignment of data across mission-critical systems

TD-7 Degree of USCDI Improved Interoperability and Exchange and Its Limitations

USCDI has contributed to the improvement of standardized core elements and exchange across EHRs, but the pace of standardization remains slow and the transition to standards has not significantly resolved or reduced preventable medical errors. Additionally, there is a need for unstructured patient data to become more visible and useful.

TD-7.a, TD-7.b, and TD-7.c Expanding USCDI and Other Limitations

USCDI misses SDOH, caregiver data, and detailed behavioral health records critical for holistic care and analytics. Existing limitations need to be addressed by expanding the scope of USCDI, through conformance testing, and standard implementations.

Data elements should be added with a plan to improve defined outcomes and measures. A timeline of at least 6-18 months is necessary for organizations to work with technology vendors to implement changes depending on whether it uses data that is already collected and stored in the EHR and/or available via FHIR.

TD-7.d Non-Proprietary but Less Structured Formats

A less structured format is not preferable. We recommend semantically structured formats for data exchange standards such as EHI, USCDI and FHIR. For unstructured data, we recommend exploring how Large Language Models (LLMs) can promote the processing and sharing of valuable data that is contained within these documents/free text notes/etc.

TD-9.a Benefits of Redefining Certification to Prioritize API-enabled Capabilities Over Software Functionality

The most impactful benefits of changes to CMS certification would be best focused on:

- Expanding data interoperability between systems with a focus on APIs
- Clinical outcomes and safety (especially true for EHR during inpatient care where necessary data is local)

TD-11.a, TD-11.b, and TD-11.c EHI Export Limitations and Suggestions

The EHI export standard should be revised as follows:

- Require certified health IT developers implement requirements according to an implementation guide for standardized APIs
- Allow patients, not just providers, to initiate requests
- Advance single patient EHI export standard to further empower patient-initiated data exchange activities
- Expand TEFCA so QHINs can use standards to move beyond document-based, view-only information exchange

Data Exchange

TD-13 New Opportunities and Advancements with API Access to Patient's EHI

Patient health data accessibility opens the door to generative AI coaching and generic care. True patient-centric care will be achieved with a combination of AI capabilities. Advanced analytics and machine learning (ML) have been capable for some time of driving new models of care but have lacked data. Data is the core asset of healthcare information, and complete data is needed for true individual-centric care.

TD-13.a Primary Obstacles

CMS must address or facilitate handling unstructured data types and remove vendor silos around blocking and proprietary implementation of standards. Privacy can be addressed through existing rules and regulations, as the issue is not the sharing of patient data, which already occurs, but the need for usable interoperability.

TD-13.b Primary Tradeoffs Between USCDI and EHI

A focus on a single standard and process is required so outcomes for which the standards exist are created. Multiple standards and methods create a barrier to achieving the Quadruple Aim and interoperability.

TD-19, TD-19.a and TD-19.c Shortcomings and Improvements for Price Transparency Implementation

Improvements to price transparency requirements will improve patient trust with providers and payers which is critical to the future of healthcare. Some shortcomings include:

- Limited consumer understanding and ease of access to the data
- Variation in data formatting and accessibility leads to difficulties with using data to inform decision-making
- Narrow scope of services that require reporting

Recommended improvements:

- Proactive marketing and communications to patients for price transparency information
- Measuring how consumers are using information to reduce the total cost of care, cost to the patient, and cost to the payer
- Seeking standard and specification feedback for reporting requirements to improve the usability of the data reported
- Flexible reporting method to reduce burden and increase publicly available data accuracy to allow raw data reporting via APIs aggregated and calculated on behalf of a reporting entity

VALUE-BASED CARE ORGANIZATIONS

Digital Health Adoption

VB-1 Incentives for APMs, ACOs, and MSSP Participants to Adopt Digital Health

A variety of digital tools are available to aid participants in VBC programs (e.g., APMs, ACOs, and Medicare Shared Savings Program (MSSP) to improve population health and achieve better cost and quality outcomes. These tools help risk-stratify patients, securely communicate across care teams, outreach to patients and caregivers, and aggregate various data sources (e.g., claims, EHR, scheduling, HIE data, medication refills, imaging, labs) into actionable insights at the point of care.

Obstacles to adoption at the participant level include financial and human resourcing, change management expertise, and technical compatibility. Many value-based care organizations serve as aggregators and enablers, reaping financial gains in the form of a portion of shared savings or other fees charged to participating providers. In return, these organizations offer resourcing and change management support and navigate the technology challenges collaboratively with providers. There is a balance to be struck between delivering these critical enablement services. Many providers (e.g. small independents) cannot participate in VBC without the cut of shared savings/incentive payments that funds the large VBC organizations.

CMS has several options to consider, including:

- **Link incentive payments to use digital health:** 1) develop specialized participation tracks with added incentive payments linked to the use of data, 2) include digital health capabilities as a participation requirement, and/or 3) offer grants to model participants to adopt a platform that meets key requirements.
- **Certify VBC Organization platforms meet key standards:** CMS and ONC have established a precedent to certify third-party platforms to meet set EHR standards. They could apply the same approach to the variety of digital health platforms in existence to help enforce a level of usefulness toward meeting model goals. For example, platforms for ACOs could be required to demonstrate capabilities to enhance care navigation or to provide insight into patient-specific risks that could impact readmissions.
- **Facilitate change adoption support:** Making actionable data available is a first step toward enhancing VBC outcomes. Change management support such as coaching providers on how to leverage the data in their daily workflows is a needed service many VBC organizations provide, but consistency varies. By continuing to offer action and affinity groups through existing learning programs, CMS can aid providers in overcoming this hurdle. Where resourcing is an issue, CMS could incorporate in grant applications for technology adoption a management plan with key expected milestones.
- **Expand data to offer timely, actionable insights:** A key value proposition of VBC organizations is to expand available data to include other sources beyond claims and EHRs, such as ADT feeds, prescription medication fill data, lab and imaging data, patient-generated and provided data, patient satisfaction data, and SDOH. If CMS and ONC were to partner to certify digital platforms, these data sources could be listed as key components with timeliness standards.

VB-2 Better Integration of Key Themes and Technologies for Engagement into APM Requirements

The use of AI and advanced analytics can support population health through enhancing risk stratification, care coordination, quality measurement, and patient engagement. Additionally, research and modeling – some of the most time-consuming and arduous in APM design and implementation – can be simplified. Possible use cases include:

- **Accelerated Literature Reviews:** Use AI to rapidly process and synthesize academic articles, policy documents, and gray literature to extract key insights, reducing what traditionally takes months into days or even hours. Identify relevant studies, extract methodologies, outcomes, and conclusions, and cluster them by themes or models of care (e.g., bundled payments, ACOs).
- **Dynamic Environmental Scans:** Train a Large Language Model (LLM) to perform real-time environmental scans across academic databases, government publications, think tank reports, and healthcare news to track evolving best practices. Streamline updates to findings and flag emerging trends, regulatory shifts, or evaluation findings. Categorize evidence by impact (e.g., cost savings, quality improvements, patient outcomes), setting (e.g., primary care, specialty care), and population (e.g., Medicaid, MA). Identify gaps in the evidence base, helping researchers and policymakers target areas where new models or additional data are needed.
- **Accelerating Actuarial Modeling:** Traditional actuarial modeling is resource-intensive, often requiring manual data preparation, assumption setting, and iterative testing. Opportunities to streamline: 1) automating data ingestion and normalization from diverse sources—EHRs, claims, SDOH datasets—enabling faster and more comprehensive inputs, 2) learning from historical data to quickly identify relevant cost drivers and care patterns that impact financial outcomes, and 3) generating dynamic simulation scenarios (e.g., changes in readmission rates, chronic disease management interventions) in real-time, reducing modeling cycles from weeks to hours. This allows policy leaders to assess multiple “what-if” care strategies with speed and confidence.
- **Enhancing Precision and Adaptability:** Model teams may adapt an APM to emerging trends—such as shifts in utilization patterns, new treatment protocols, or evaluation results. Unlike static actuarial assumptions, opportunity exists for continuous learning, improving predictive accuracy and allowing granular forecasting of cost and risk at the population or individual level and tailored interventions by identifying subpopulations most likely to benefit financially and clinically from specific care models.

VB-3a and VB-3b Essential Health IT Capabilities for Value-Based Care Arrangements

New IT capabilities for value-based care are most effective when they enhance user experience, reduce provider burden, integrate seamlessly with value-based care workflows, comprehensive data access, robust analytics, and have key features such as a timeline for proactive engagement. Key recommendations for health IT capabilities for VBC include:

- New triggers for patient mediated exchange of the full patient EHI export using APIs to enhance access to a comprehensive medical record
- Timely event notifications using FHIR subscriptions to enable more proactive sharing of

valuable events such as a patient change in address or inpatient admission

- Encompassing data extraction and normalization into a longitudinal patient-centered summary
- Increasing meaningful quality measures data
- Access to claims data, attribution, and patient ID matching, and enabling interoperability for remote device data
- Patient event notifications that can be subscribed to by type and system using standard FHIR subscriptions

VB-4 Essential Data Types Needed for Successful Participation in VBC

There is a need to increase access to data beyond claims and EHR data. CMS should consider the timeliness of data provided as an essential component for making data actionable to VBC participants. Data types and timeliness considerations are included in the table below:

Data Type	Recommended Timeliness
Admission, Discharge, Transfer (ADT) Feeds	Daily
Medical Data Management (MDM) Feeds	Daily
Lab and Imaging Results	Daily
All Payer Pre-Adjudicated and Paid Claims	Weekly
Medicare Advantage/Medicare Operations (MOR/MAO) Files for Risk Adjustment	Monthly
Grievances Data and/or Consumer Assessment of Healthcare Providers and Systems (CAHPS) Patient Satisfaction Data	Monthly
Low-Income Subsidy (LIS) Data	Monthly
Attribution, Demographic, and Roster Files	Monthly

Additionally, CMS might consider implementing accepted standards or universally recognized criteria for assessing data quality and confidence when integrating data from multiple sources. These criteria could consider factors such as the type of data, its source, context, author, and timing to determine the veracity of the data. With this approach, quality and reliable data is used to make informed healthcare decisions.

Compliance and Certification

VB-5, VB-6, and VB-7 Compliance and Certification for VBC

CMS and ONC have established a precedent through the certified EHR technology (CEHRT) Program. This program provides a solid foundation for VBC by mandating capabilities like Meaningful Use, EHR interoperability, standardized APIs (e.g., FHIR), and patient data access. For example, certified EHRs support USCDI standards so key data like lab results or medications can be exchanged across systems. The program's focus on patient portals also aligns with VBC's emphasis on engagement. Overall, the certification program has helped improve the quality of

information available to providers, but hurdles such as speed of certification, burden on smaller ACOs of compliance costs, and varied usability experiences remain. Options for CMS to consider include:

- Implementing requirements and/or incentives by Focusing certification efforts on enablers/aggregators (as referenced in VB-1)
- Incorporate requirements on patient-centric outcome documentation at the point of care to arm providers with actionable insights for ongoing care and quality measures
- Reward or require expansion of data availability and timeliness, as referenced in VB-1 and VB-4 to enhance participant data use and break down silos across disparate care settings and teams
- Reduce burden and alignment with workflows by meeting certification criteria and reducing disruptions to clinical workflows. For example, avoiding the creation of quality measurements specific to certain populations to the point of care to avoid provider workflow disruption and increase the burden on HIT users, particularly clinicians.

VB-8 HHS Policies to Supplement CEHRT Requirements to Better Optimize Use of Digital Health Products in APMs and Barriers for APM Participants

To more rapidly advance the use of digital health products in APMs, CMS should consider adding requirements to the Conditions of Participation for hospitals as follows:

- Expand 42 CFR 482.24(d) to mandate that hospitals not currently using an EHR to use other more cost-effective digital health products to meet the intent of the requirement, rather than waiving the requirement
- Expand existing requirement to more than just ADT data while still providing flexibility
- Expand the definition in the rule to include additional recipients of the event notifications to further engage the ACO's care team

Barriers and recommendations for notifications include:

- Alert fatigue and ability to subscribe to notifications by both type of notification and type of systems
- Feedback loop by using an acknowledgement feature to prevent redundant notifications, reduce alert fatigue and improve the experience for recipient
- Subscribing systems are not required to acknowledge or act upon the receipt of the ADT message, making it difficult to measure the effectiveness and impact of this very important lever that CMS has
- CMS should consider working with HL7 to further enhance the ADT notifications using existing vocabularies and semantic definitions to improve how APM participants use the ADT data to improve patient outcomes per the ACO model

VB-9 Technology Requirements for APM Organizations When Comparing to Non-APM Organizations (for Example, Quality Reporting, and Interoperability)

Technology requirements for APM organizations:

- For increased adoption and use, tailor technology requirements for APM organizations to

improve outcomes and decrease costs

- APM Technology solutions present information to the provider or patient in a way that facilitates action

For instance, technology can present different ways to treat a disease along with their relative costs. As coverage status of a patient's formulary benefit is displayed when a clinician prescribes medication, the coverage status of diagnostic and treatment services tailored to a patient's financial coverage can be displayed to the clinician at the point of decision (POD). Implementing this benefit display at the POD or on demand is a feasible technology solution.

Offer real-time, clinician-facing service benefit management tools. These tools can be coupled with CDS alerts that identify potential adverse situations by evaluating a patient's services, medications, devices, and conditions in relation to prospective orders or interventions. This approach provides clinicians with the necessary information at the critical moment of decision-making.

VB-10 Certification Criteria and Flexibility for Advanced APMs and Rural Providers

To encourage both participation and results, CMS can utilize specific flexibilities for Advanced APMs and flexibilities and alternatives for rural providers. Recommendations for certification criteria include:

- Identifying a subset of certification criteria that is relevant to clinical practices of Advanced APMs. This can include interoperability standards, patient engagement tools, and data reporting capabilities that align with the clinical focus of the APM
- Functionalities like electronic prescribing, secure messaging, CDS, and patient access to EHI
- Standardize fields/formats for common quality measures by using the HL7 Quality Reporting Document Architecture (QRDA) standard for a set of measures
- Reinforce criteria that supports EHR to directly submit quality data for a set of measures across programs to reduce reporting burden
- Build actionable insights into a dashboard-like view for care teams to flag risks, outreach needs, etc.

Flexibilities and/or Alternatives for Smaller or Resource-Constrained Providers**:**

- Modular Certification allows smaller providers to adopt tailored modular CEHRT solutions without requiring full-scale EHR systems
- Financial Assistance through grants or subsidies to smaller and rural providers to help with the costs associated with CEHRT implementation and maintenance
- Technical support programs to help smaller providers implement and enhance CEHRT systems
- Phased Implementation to allow providers to implement CEHRT functionalities in phases, prioritizing the most critical components first
- Encourage the use of shared EHR services or regional HIEs to reduce the burden on individual small practices by sharing resources and provide incentives accordingly

Technical Standards

VB-11 Interoperability Challenges Encountered in Implementing Value-Based Care Programs

Challenges encountered include inadequate data due to the lack of agreed upon and universally adopted data standards for real-time exchange of patient level data. CMS should continue to encourage and require the HL7 QRDA for quality measures related to data across programs and FHIR-based standards. This will allow care gaps to be evaluated in near real time at the individual level and is the best way to effect positive quality change and improved outcomes in value-based care programs.

VB-12 and VB-13 Improvements to Standards and Certification Criteria for APM Technology Implementations

To preserve program-specific flexibility while promoting innovation in APM technology implementations, the following can be considered:

- Adopt and provide incentives for widely recognized interoperability standards such as HL7 FHIR so different health IT systems can communicate and share data seamlessly. Encourage the use of APIs to facilitate data exchange between systems that are near real-time and tailored to the transaction (e.g. remote monitoring). Make these implementation guides public through standards such as HL7.
- Standardizing capabilities that support patient-centered care, such as patient portals, secure messaging, and PGHD. Deliver patient access to their own health information and can share it with their care providers.
- Standardizing outcome-based measures rather than process measures to allow providers flexibility in how they achieve desired outcomes. Encourage the use of health IT that supports quality reporting and performance measurement, to include the HL7 QRDA standard.
- Encourage development and adoption of innovative technologies by providing clear guidelines on integrating and certifying new technologies within the APM framework. Allow pilot programs and sandbox environments where new technologies can be tested and refined before full-scale implementation. Support pilot programs and innovation grants that allow providers to test and implement new technologies and care models.
- Promote vendor-neutral standards so providers are not locked into specific vendors or proprietary systems. Encourage use of open standards and open-source solutions where appropriate.
- Offer technical support and training programs to help providers implement and enhance their health IT systems. Create resources and toolkits that guide providers in meeting CEHRT requirements and leveraging health IT for value-based care.

Certification criteria should be flexible with a focus on reducing burden such as:

- Encourage development of intuitive and user-friendly health IT interfaces
- Consolidate criteria for reporting requirements across programs
- Support partial or modular certification for APM functions such as value-based care, decision support tools, population health management and care coordination tools

- Outcome-based measures to reflect quality and effectiveness of care and encourage the use of risk-adjusted outcome measures to account for patient complexity and variability
- Provide flexibility in how providers meet CEHRT requirements

Consider criteria that encourage the use of natural language processing (NLP) and other advanced technologies to automate documentation and data entry processes.

VB-14 Digital Identity Credentials Impact on Value-Based Care and Outcomes

Overall, digital identity credentials enhance the security, efficiency, and effectiveness of value-based care delivery, leading to better patient outcomes and satisfaction by addressing several key areas:

Enhanced Security and Privacy:

- Reduces the risk of data breaches and unauthorized access by only allowing authorized individuals to have access to sensitive patient information
- Strong authentication mechanisms, such as multi-factor authentication (MFA), helps protect patient data and maintain trust in the healthcare system

Streamlined Access to Patient Information:

- Allows healthcare providers to quickly and securely access patient records across different systems and care settings
- This seamless access to comprehensive patient data supports better clinical decision-making and care coordination, leading to improved outcomes

Improved Care Coordination:

- Allows healthcare providers to share patient information with other members of the care team, including specialists, primary care providers, and ancillary services
- Timely and appropriate care coordination interventions reduces the likelihood of redundant tests and procedures for patients

Patient Empowerment and Engagement:

- Enables patients to access their own health information and manage their care more effectively
- Secures patient communication with healthcare providers to communicate, schedule appointments, and access educational resources

Reduction in Administrative Burden:

- Automates and streamline administrative processes, such as patient registration, consent management, and billing
- Reduces the administrative burden on healthcare providers allows them to focus more on patient care, improving the overall quality of care delivery

Support for Telehealth and Remote Monitoring:

- Facilitates secure access to telehealth services and remote monitoring tools, enabling

providers to deliver care to patients regardless of their location

- Improving access to care and health outcomes especially for patients in rural or underserved areas

Compliance with Regulatory Requirements:

- Healthcare organization compliance to data security and patient privacy, such as HIPAA
- Protects patient information and helps healthcare providers avoid potential legal and financial penalties

VB-15 Nationwide Provider Directory Benefits, Key Data Elements and Standards

A nationwide provider directory with FHIR endpoints can support a variety of efforts for both patients and providers. Benefits include:

- Reduction of administrative burden and errors in claims processing, leading a streamlined and less costly administrative process
- Improvements in access to geographic and telehealth offering information, benefiting rural or underserved areas
- Care coordination to identify and connect with appropriate specialists and services as needed for comprehensive care

Key Data for a Nationwide FHIR Endpoints Provider Directory:

- Endpoint Information:
  - URL of the FHIR endpoint
  - Supported FHIR versions
  - Security and authentication requirements (e.g., OAuth, API keys)
- Provider Information:
  - Provider name and organization
  - Specialties and services offered
  - Contact information (e.g., phone number, email address)
- Geographic Information:
  - Location details (address, city, state, ZIP code)
  - Service areas covered
- Certification and Accreditation
  - Details of any certifications or accreditations held by the provider or organization
- Data Types and Formats:
  - Types of data available (e.g., clinical notes, lab results, imaging)
  - Supported data formats and standards
- Availability and Performance Metrics:
  - Availability status of the endpoint (e.g., up-time, maintenance schedules)

  - Performance metrics (e.g., response times, data transfer rates)
- Compliance and Regulatory Information:
  - Compliance with relevant regulations (e.g., HIPAA, GDPR)
  - Data privacy and security policies

Furthermore, CMS can consider relevant Health IT Standards for Provider Directories to support as many uses cases as possible while leveraging a common solution:

- HL7 FHIR “Endpoint” resource for representing provider directory information
- IHE IT Infrastructure Technical Framework and IHE Healthcare Provider Directory (HPD) profile defines a standardized approach for managing and sharing provider directory information
- NCPDP (National Council for Prescription Drug Programs) format standards for Provider Identification and directory services in the context of pharmacy services and electronic prescribing
- X12 (Electronic Data Interchange) X12 standards include transactions for provider information, such as the X12 274 transaction set, which is used for healthcare provider information
- CAQH CORE (Committee on Operating Rules for Information Exchange) CAQH CORE operating rules include standards for provider data exchange and directory updates, aiming to improve the accuracy and efficiency of provider directories