Digital Quality Measurement Strategic Roadmap

March 2022

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Executive Summary

Background

The Centers for Medicare & Medicaid Services (CMS) implements quality measurement programs across a broad range of inpatient and outpatient care settings as mandated by Congress and consistent with its mission.[1] These programs provide incentives for and/or penalties for performance on quality measures, contribute to improvements in health care, enhance patient outcomes, inform consumer choice, and promote transformation to a digital health ecosystem. Over the past decade, CMS has advanced the use of data from electronic health records (EHRs) to enhance and expand quality measurement. However, accessing clinical patient data from EHRs for the purpose of quality reporting remains burdensome.[2] Additionally, CMS's current approach to quality measurement does not easily incorporate emerging digital data sources such as patient-reported outcomes (PROs) and patient-generated health data (PGHD). There is a need to streamline the approach to data standardization, collection, exchange, calculation, and reporting to fully leverage clinical and patient-centered information for measurement, quality improvement, and learning.

Advancements in the interoperability of healthcare data from EHRs create an opportunity to dramatically improve CMS's quality measurement systems and realize creation of a learning health system. In 2020, the Department of Health and Human Services (HHS) finalized interoperability requirements in CMS's Interoperability and Patient Access final rule and in the Office of the National Coordinator for Health Information and Technology's (ONC's) 21st Century Cures Act final rule.[3-5] These changes, driven by the Cures Act's goal of "complete access, exchange, and use of all electronically accessible health information," will greatly expand the availability of standardized, readily accessible data for measurement. Most important, CMS's and ONC's interoperability rules and policies require specified healthcare providers and health plans to make a defined set of patient information available to authorized users (patients, other providers, other plans) with no special effort using Fast Healthcare Interoperability Resources (FHIR®) application programming interfaces (APIs). The scope of required patient data and standards that support them will evolve over time, starting with data specified in the United States Core Data for Interoperability (USCDI) Version 1, structured according to the Health Level Seven International (HL7®) FHIR US Core Implementation Guide (US Core IG).

This increasing availability of structured, FHIR-formatted EHR data exchanged through FHIR APIs can be leveraged to greatly reduce long-standing challenges to quality measurement. Currently, implementing individual EHR-based measures requires providers to install and adapt measure calculation software in their respective EHR systems, which often use variable or proprietary data models and structures. This process is burdensome and costly, and it is difficult to reliably obtain high-quality data across EHR instances. Once providers map their EHR data (structured using a uniform FHIR standard) to a FHIR API to meet the Cures Act requirements, it will be possible to exchange much of the foundational data

needed for measures without significant additional provider investment or effort. Learnings from these activities can be leveraged and applied to other digital data that live outside the clinical EHR, enhancing and expanding the use of data such as PRO and PGHD for quality measurement in the future.

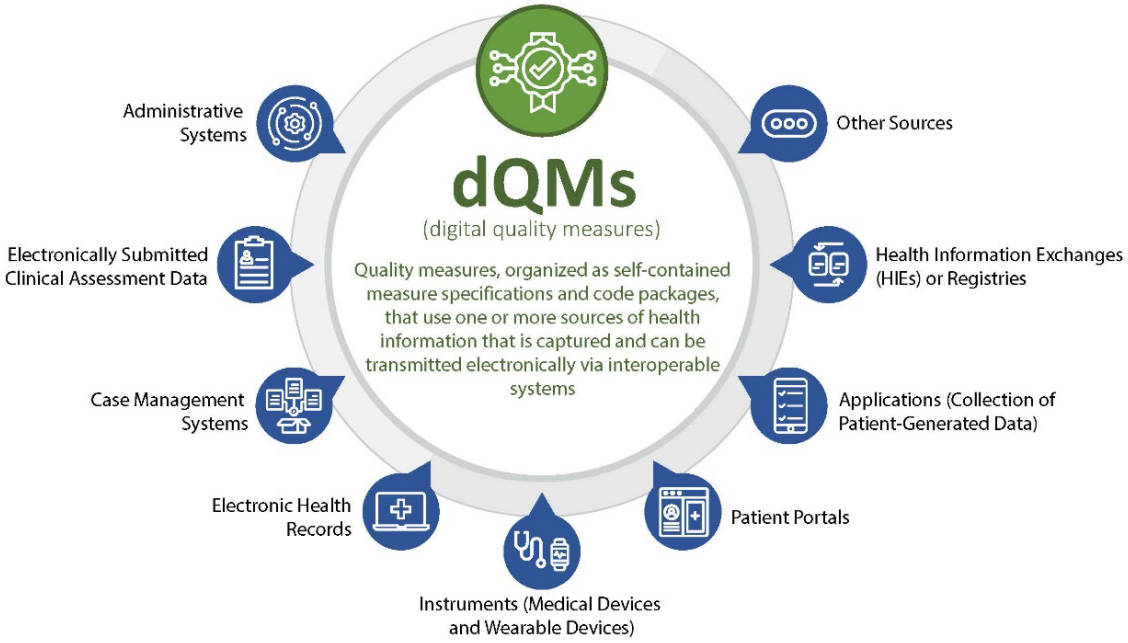
The advances in interoperability will enable development of measure calculation tools (MCTs) for digital quality measures (dQMs) that solely use EHR data, so providers will no longer need to install measures one-by-one and update them annually in their unique EHR systems. Measures can be self-contained tools executed by the provider on-site, and by multiple other key actors in measurement — including CMS, other payers, clinical registries, and data aggregators. This approach to measurement tools could reduce provider measurement burden, facilitate the cross-provider aggregation of data needed for high-priority measures such as outcome measures, and support the alignment of measures and data across multiple agencies and payers. In the future, interoperability of EHR and other digital health data can fuel a revolution in healthcare delivery and advance MCTs to leverage data beyond just EHRs and across settings and providers. A learning health system powered by advanced analytics applied to all digital health data can optimize patient safety, outcomes, and experience.

Transition to Digital Quality Measurement

Building on advances in interoperability, CMS intends to transition to digital quality measurement through the actions outlined in this Digital Quality Measurement Strategic Roadmap (dQM Strategic Roadmap). We recognize that providers and care settings are at different stages of readiness, and that the timing of implementation to dQMs across the different quality reporting programs may vary. We anticipate the transition will be paced with the uptake of FHIR API technology. CMS defines dQMs as quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that are captured and can be transmitted electronically via interoperable systems (Figure 1). dQMs improve the patient experience by improving the quality of care, the health of populations, and by reducing costs. Data sources for dQMs may include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), Health Information Exchange Organizations (HIEOs) or registries, and other sources. Electronic clinical quality measures (eCQMs), which use EHR data, may be refined or repackaged to better fit within the dQM umbrella. While eCQMs meet the definition for dQMs in many respects, limitations in data standards, requirements, and technology have limited their interoperability and continue to levy a significant administrative cost for implementation beyond that required for the provision of clinical care.

Future dQMs will query the data needed (for example, from FHIR APIs), calculate the measure score, and generate the required reports. Leveraging advances in technology (for example, FHIR APIs) to access and electronically transmit interoperable data for dQMs will reinforce the aggregation of data across multiple data sources, rapid-cycle feedback, and alignment of programmatic requirements. Deployment of dQMs as testable code packages could also support agile development and flexibility in tooling (for example, enables progress toward incorporating natural language processing [NLP] and other advanced analytic approaches to incorporate unstructured data into measures), and facilitates the broader use of tools developed for quality measurement for other related activities such as quality improvement and research.

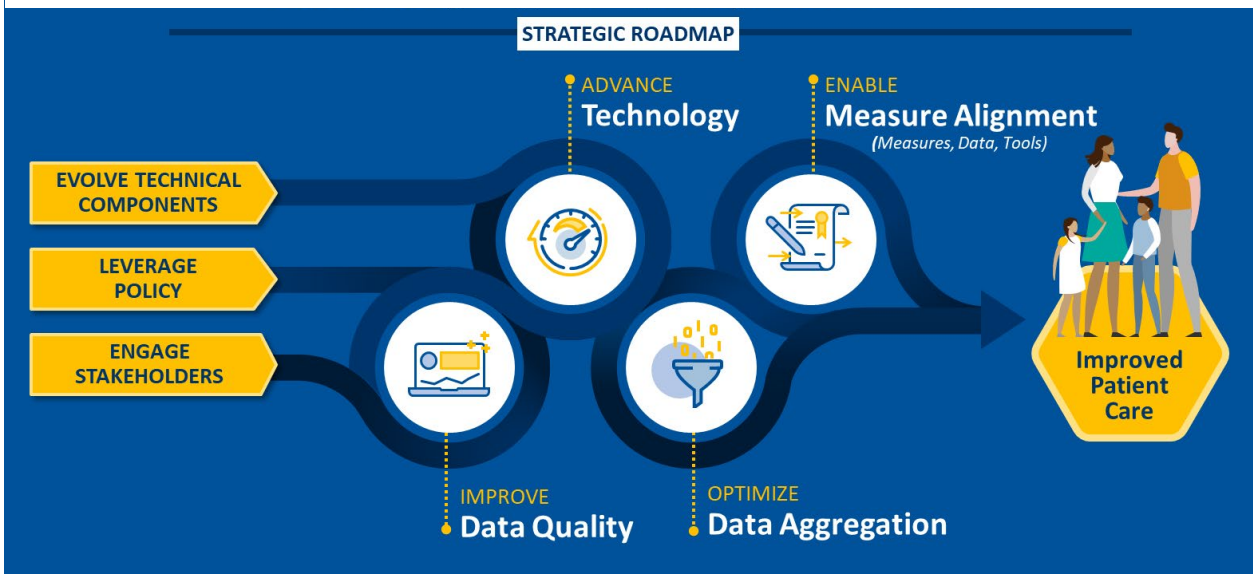
Figure 1. dQM components. *dQMs utilize one or more sources of health information that are captured and can be transmitted electronically via interoperable systems.*



Changes under Consideration to Advance Quality Measurement

CMS intends to modernize the quality measurement enterprise in four major ways: 1) improve accuracy and expand the standardization, transmissibility, and use of digital data accessible via standards-based APIs; 2) redesign quality measure data collection, calculation, and reporting with self-contained MCTs; 3) modernize processes to optimize data aggregation; and 4) better align measures, data requirements, and tools across reporting programs, federal and state programs and agencies, and the private sector (Figure 2). CMS will engage external stakeholders for input and collaboration opportunities.

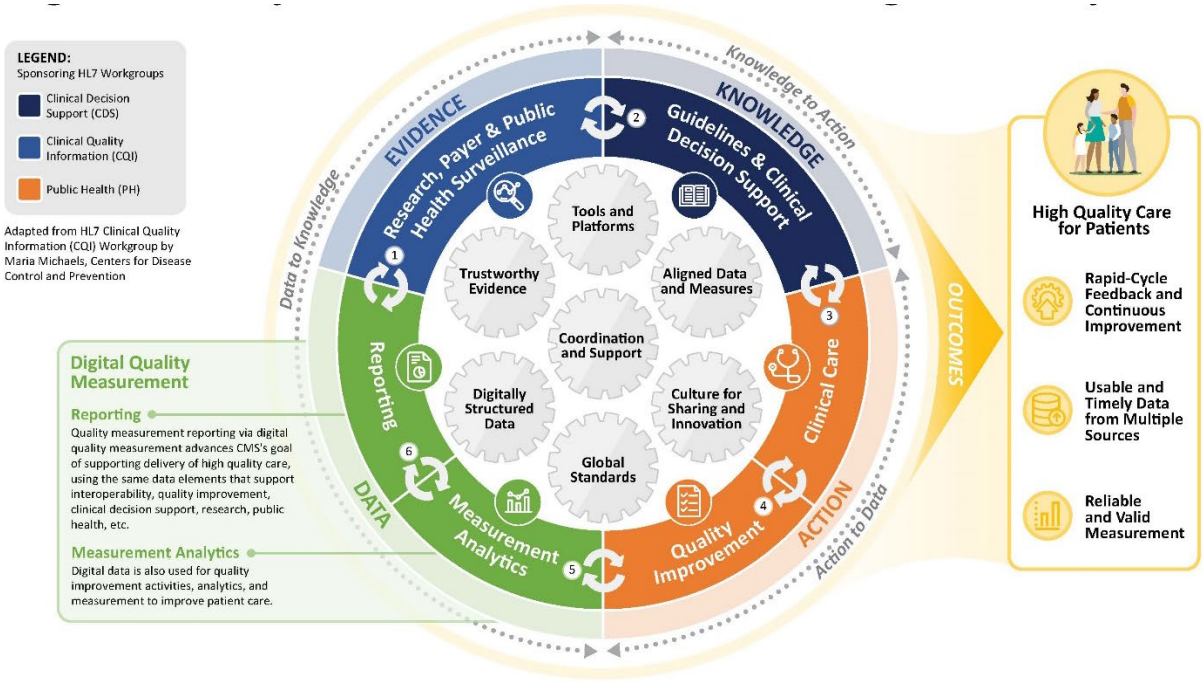
Figure 2. Four domains to transition to dQMs. *For each of the four identified domains — 1) improve data quality; 2) advance technology; 3) optimize data aggregation; and 4) enable measure alignment — CMS will work to evolve technical components, leverage policymaking, and engage stakeholders. Advancement in these domains will lead to improved patient care.*



These changes will advance digital quality measurement in several ways. First, they will foster greater ease and efficiency of data collection and reporting by leveraging interoperability and data standardization within providers' EHR systems. Second, self-contained MCTs for CMS measures could interact with providers' FHIR APIs, perform the logic steps required of the measure, and create a report of results. This modified approach could eliminate the current requirement that providers create and deploy each individual measure required for CMS quality reporting manually in their unique EHR. Third, the changes will expand the opportunity for various data aggregators to analyze data and foster learning at the local, state, regional, and federal levels. Finally, the advancements will enable quality measure alignment and alignment with quality improvement, public health, research, and clinical decision support, as various regulators and payers gain easier access to the broader set of data required for common accountability measures.

Although not detailed in this report, CMS will, in parallel, continue to advance efforts to digitally capture and make interoperable other data, such as PROs and PGHD from multiple healthcare delivery settings including community agencies and homes. Once all these data can be captured, validated, shared, and merged for analysis, we will be poised to deliver on the promise of a learning health system. In a learning health system, standardized and interoperable digital data from a single point of collection can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. Data used for quality measurement, as well as these other use cases, should be a seamless outgrowth of data generation from routine workflows. Data sharing should be standards-based to maximize interoperability, minimize burden, and facilitate the development and use of common tooling across use cases. This approach supports data analysis, rapid-cycle feedback, and quality measurement that are aligned for continuous improvement in patient-centered care (Figure 3).

Figure 3. Digital quality measurement in a learning health system*. This figure describes the cyclical progression of patient data in a learning health system to achieve continued feedback for and improvement in patient care. The cycle includes: 1) leveraging data to inform research, payer, and public health surveillance, 2) translating these results into clinical guidelines and clinical decision support; 3) transforming clinical care; 4) using the data for quality improvement; 5) interpreting and applying the data to support measurement and analytics; and 6) reporting. These actions will lead to improved patient outcomes and the delivery of high-quality care for patients as outlined to the right of this figure.*



Actions in Four Domains to Transition to Digital Quality Measures

CMS's strategy for digital measure transformation (by improving data quality, advancing technology, optimizing data aggregation, and enabling measure/data/tools alignment) requires that we evolve technical components, leverage policies, and engage stakeholders. This dQM Strategic Roadmap outlines the actions within four key domains (Figure 2) that will enable this transformation.

IMPROVE DATA QUALITY: Improve accuracy and expand the standardization, transmissibility, and use of digital data accessible via standards-based APIs

CMS aims to build on advances in EHR data interoperability to advance dQM goals, including using higher quality, standardized, and accurate data. The requirements set by CMS and ONC for certain EHR data to be exposed in the FHIR standard is a critical advancement to interoperability and quality measurement. CMS will fully leverage these requirements to adapt eCQMs and expand to other dQMs through the adoption of interoperable standards across other digital data sources including PGHD and PROs. The act of standardizing data is more critical to the advancement of data sharing and use than the specific characteristics of the standard adopted. Once data are standardized across providers, settings, and data type, they can be more easily mapped to new and emerging standards over time. This initial

step of mapping and standardization is a threshold event for advancement to a learning health system. CMS intends to optimize and accelerate this process to support all critical health information.

ONC continues to evolve the USCDI requirements for EHR data necessary to be interoperable using FHIR standards with the release of several USCDI versions, expanding the inventory of data elements that should be standardized. In addition, recognizing that USCDI will not be able to meet all unique agency or use case-specific data needs, ONC created the United States Core Data for Interoperability Plus (USCDI+),[6] which will support additional datasets or extensions beyond what is captured within the USCDI. Initial efforts to enable federal partners to establish and harmonize these datasets will begin with the Centers for Disease Control and Prevention (CDC) and CMS. To advance the use of standardized data, models, implementation guides, and value sets in quality measurement, CMS will focus on leveraging the interoperability data requirements for APIs in certified health information technology (IT) (USCDI), set by the ONC 21st Century Cures Act final rule,[3] and the additional nationwide standardization efforts (USCDI+) as vehicles to support modernization of CMS quality measure reporting. As needed, CMS will also consider other supplemental data requirements (for example, specified in FHIR Quality Improvement (QI) Core Implementation Guide) and governance processes to define additional data critical for measurement that are not included in the USCDI or USCDI+ and that come from other sources outside of the EHR.

High quality data are essential for reliable and valid measurement. Hence, in implementing the shift to capture all clinical data from EHRs via FHIR APIs, CMS will support efforts to strengthen and test the quality of the data obtained through FHIR APIs for quality measurement. CMS currently audits electronic data for completeness and accuracy, proper data formatting, alignment with standards, and appropriate data cleaning. In a fully digital system, CMS will consider audit compliance with these requirements electronically and potentially further automate manual validation of data against the original data sources (for example, medical record) where possible. Health IT and analytic advancements can support this evolution, such as NLP, big data analytics, and artificial intelligence (AI). These techniques can be applied to validating observed patterns in data and inferences or conclusions drawn from associations.

ADVANCE TECHNOLOGY: Redesign quality measure data collection, calculation, and reporting with self-contained measure calculation tools

CMS seeks to redesign its eCQMs, which are a subset of dQMs, as open-core (open source core architecture that does not require proprietary access to operate), self-contained tools (MCTs) that could retrieve data from FHIR and other resources maintained by providers, payers, CMS, and others. Similar to the CDC's Making EHR Data More Available for Research and Public Health (MedMorph) project, these MCTs could be formatted to retrieve the data from providers' FHIR API endpoints. The tools would perform three functions: 1) obtain data via automated queries from a broad set of digital data sources (initially from EHRs, and in future years from additional sources including PRO and PGHD) and format it for analysis; 2) calculate the measure score according to measure logic, including identifying patients eligible for measure cohorts, assessing outcomes, and calculating measure scores; and 3) generate required output. The MCT can be housed without special installation effort within individual providers' health IT systems; implemented by external health IT vendors, data aggregators, and health plans; and/or run by CMS depending on the program and measure needs and specifications. If CMS pursued the creation of MCTs, development and testing would include demonstrating in HL7 Connectathons that

the tools align with ONC requirements across multiple platforms and generate the correct score for a robust set of test cases pulled via FHIR APIs. CMS will consider whether a certification process should be established that would allow others to develop, similarly test, and implement CMS-certified complementary MCTs.

OPTIMIZE DATA AGGREGATION: Modernize processes to optimize data aggregation

CMS aims to enhance and update guidelines, with input from stakeholders, to optimize third-party data aggregators in service to providers for the calculation and reporting of dQMs for CMS quality reporting programs. CMS will continue to work with third-party data aggregators to maintain the integrity of the measure reporting process. Further, CMS will continue to consume and aggregate digital data from multiple sources, including its administrative claims data, to enable broad assessments of care quality in accordance with program requirements. CMS aims to enhance its own data aggregation capacity to centralize data for multiple uses including attribution, robust data validation, quality measurement, and production of rapid-cycle feedback to providers.

ENABLE MEASURE ALIGNMENT: Better align measures, data requirements, and tools across reporting programs, federal and state programs/agencies, and the private sector

CMS will evaluate how to create and maintain a common portfolio of dQMs across our regulated programs, agencies, and private payers. This common portfolio would require alignment of: 1) the individual data elements used to build these measure specifications and calculate the measure logic and 2) measure concepts and specifications including narrative statements, measure logic, and value sets. CMS will continue to leverage existing collaborations and initiatives to align measures including: our Meaningful Measures 2.0 framework;[7] the Trusted Exchange Framework and Common Agreement (TEFCA);[8] the Federal Electronic Health Record Modernization (Department of Defense [DoD] and Veterans Affairs [VA]);[9] the Core Quality Measures Collaborative (CQMC),[10] which convenes stakeholders from America's Health Insurance Plans (AHIP), CMS, the National Quality Forum (NQF),[11] provider organizations, private payers, and consumers; and the NQF-convened Measure Applications Partnership (MAP), which recommends measures for use in public payment and reporting programs. These collaborations will be ongoing and allow for continuous refinement to ensure quality measures remain aligned with evolving healthcare practices and priorities (for example, PROs, health equity, care coordination), and track with the transformation of data collection, conformance with evolving standards and health IT modules, and adoption of technologies regulated by ONC (for example, standards-based APIs).

As alignment of measures is best supported by alignment of the underlying data, CMS will also seek agreement on a standardized portfolio of data elements to be used in dQMs in the public and private sectors, using the same collaborations and activities leveraged for measure alignment and the USCDI and USCDI+. The process will be iterative and begin with CMS programs and other HHS agencies and can expand to the private sector. Recognizing that alignment of data elements is integral to a successful transition to dQMs, CMS will initially prioritize this activity, while also determining the timeline and identifying measures to be created or modified for implementation and aligned using these standardized data and tools. CMS will continue to ensure that those dQMs that are best suited to measuring the achievement of patient outcomes are implemented in CMS quality programs.

CMS will also collaborate with HL7's ongoing work to advance FHIR resources in critical areas to support patient care and measurement such as social determinants of health (SDOH). Through this coordination, we can identify existing measures to be used or evolved for use as dQMs, in recognition of current healthcare practice and priorities.

Engage with external stakeholders on the Digital Quality Measurement Strategic Roadmap and planned modernization activities

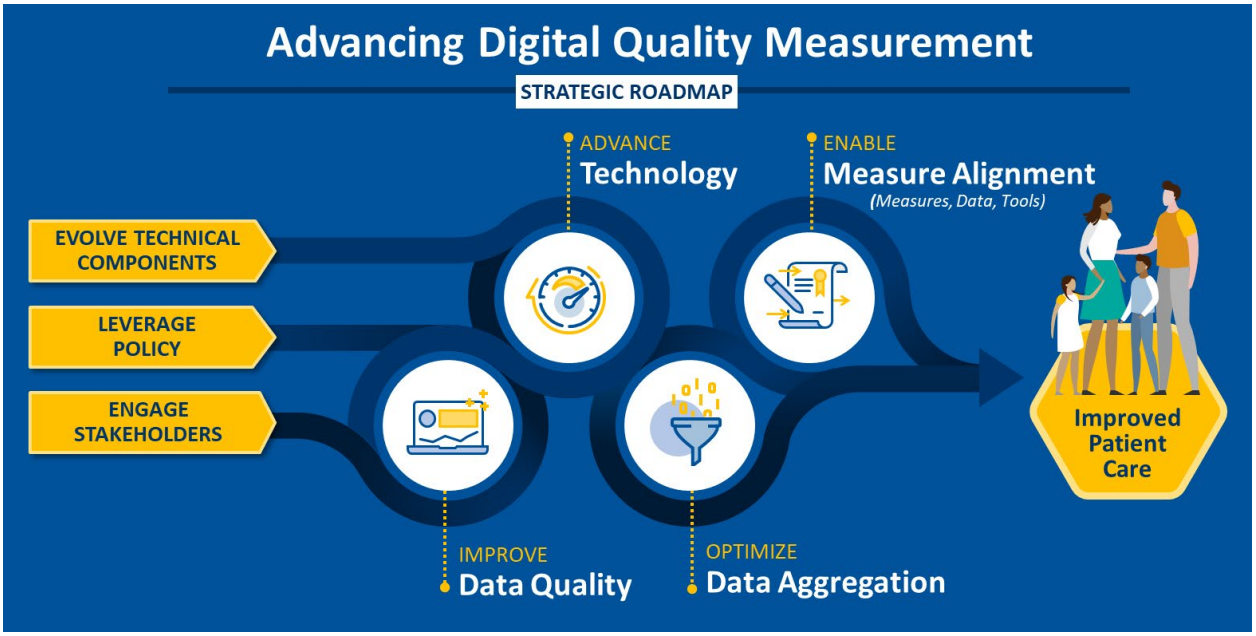
CMS will continue to collaborate within our agency and across other federal and state agencies to identify opportunities for co-creating strategies and solutions for this dQM Strategic Roadmap. We will mobilize industry stakeholders and experts based on their own experiences to facilitate mutual learning, exchange ideas for this strategy, advance data standards, and identify alignment opportunities.

This dQM Strategic Roadmap outlines the actions CMS has identified to advance digital quality measurement. These actions for improving data quality, advancing technology, optimizing data aggregation, and enabling alignment of measures, data, and tools will support quality measurement and multiple other use cases, including quality improvement efforts, clinical decision support, research, and public health. CMS will engage external stakeholders for input on and collaboration with these efforts.

Introduction

This Digital Quality Measurement Strategic Roadmap (hereinafter, dQM Strategic Roadmap) intends to advance digital quality measurement across the Centers for Medicare & Medicaid Services (CMS) quality measurement reporting programs, while contributing to a learning health system. In this report, we outline the four key domains that constitute the strategy for achieving CMS's transition to digital quality measures (dQMs) (Figure 4). Each domain seeks to address the limitations of our current system, which are well known and only partially addressed by CMS and stakeholder efforts to date. Within each domain, we describe the ideal future state and the ultimate organizing principles driving this CMS digital quality strategy. To accomplish this, we will leverage the ongoing work of CMS, the Office of the National Coordinator for Health Information and Technology (ONC), and others, and outline specific actions CMS can take to build on previous and current activities.

Figure 4. Four domains to transition to dQMs. *For each identified domain – improve data quality, advance technology, optimize data aggregation, and enable measure alignment – CMS will work to evolve technical components, leverage policymaking, and engage stakeholders. Advancement in these domains will lead to improved patient care.*



These actions create the launching points for the quality measurement enterprise to become fully digital. For example, ensuring high data quality and usability will leverage the work of the United States Core Data for Interoperability (USCDI) and United States Core Data for Interoperability Plus (USCDI+). Improving the ease of data capture and exchange for quality measurement capitalizes on Fast Healthcare Interoperability Resources (FHIR)® standards, which promote interoperability; it aligns CMS's measure reporting standards with the industry clinical data exchange framework, clinical decision

support, and uptake by the commercial community and others; and it creates lower-burden access to the "atomic" data elements and meta-data needed through simplified data mapping. Data requirements must be represented within the US Core Implementation Guide (US Core IG) and other Health Level Seven International (HL7®) FHIR Implementation Guides to enable integration into electronic systems and transmission through FHIR application programming interfaces (APIs) to facilitate data sharing. The novel measure calculation tools (MCTs) under consideration in this dQM Strategic Roadmap would rely on the increased use of FHIR APIs to allow for measure criteria to be translated, data retrieved and aggregated, and analysis completed. Data aggregation seeks to leverage the work of the Trusted Exchange Framework and Common Agreement (TEFCA)[8] and recent efforts to improve patient matching and identity resolution.[12] Each of these activities support the overall goal of increased alignment.

Figure 5. Key actors in CMS's dQM Strategic Roadmap. *CMS's success in implementing this Roadmap will rely on feedback from and collaboration with this broad range of stakeholders. A detailed list of actors and actions is provided in Appendix B.*

Success will require a broad effort to coordinate and collaborate activities within and across government agencies, providers, health information technology (IT) developers, electronic health record (EHR) vendors, private payers, patients, caregivers, and many others (Figure 5). We identify many of the key actors within each domain and provide a more detailed list in Appendix B.

DOMAIN 1: Improve Data Quality

Our Approach

Data quality and usability must be further advanced to reach the shared goal of high-quality data for use across the entire healthcare system. There are multiple public/private ongoing efforts aimed at advancing data quality. CMS seeks to further advance the availability of high-quality information for quality measurement, as one use case of standardized data in a learning health system. Accessing accurate, reliable, and standardized digital data is a prerequisite for effective measurement. Digital data will be stored, transmitted, aggregated, and used to prompt the most appropriate actions to improve patient health. To achieve these goals, we focus on three strategies:

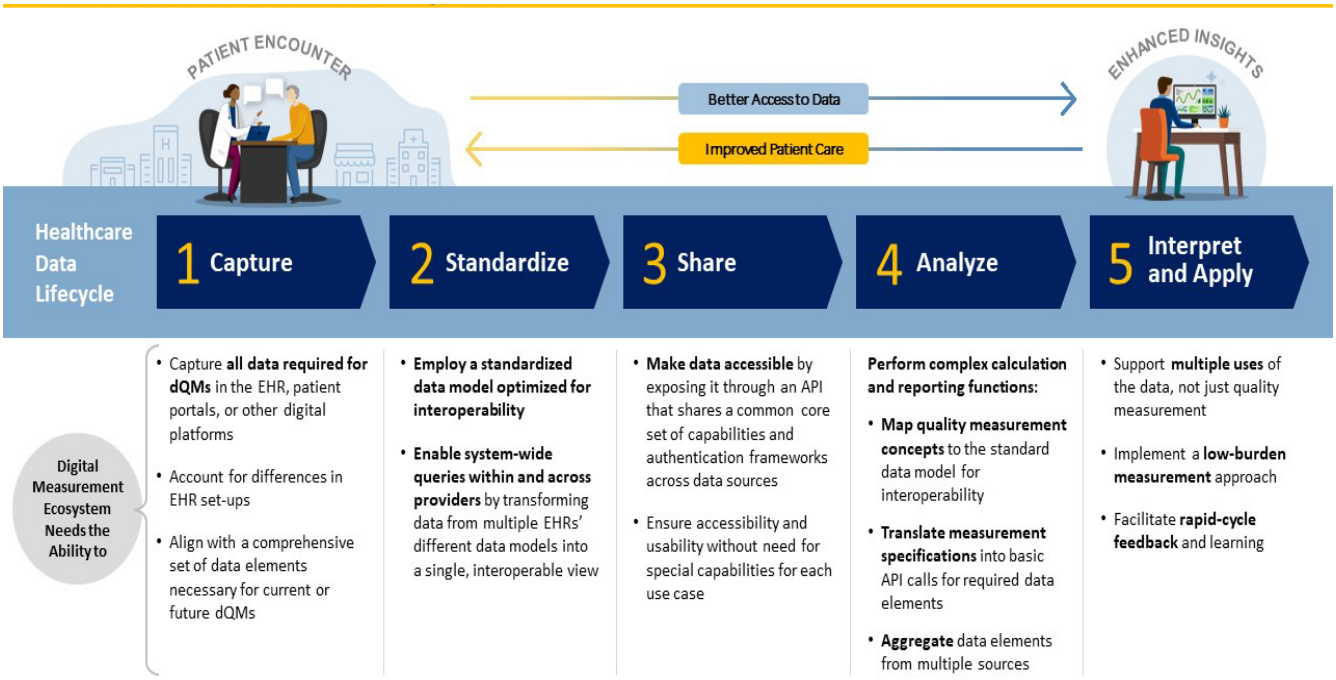
1. **Advance the standardization, transmissibility, and use of digital data**
2. **Accelerate digital capture and standardization of new data that are critical to advance quality measurement**
3. **Advance tools and processes to validate data used in measurement**

Ideal Future State – Organizing Goals

Eventually, in an ideal future state, all information for high quality healthcare delivery is captured digitally, rapidly, and through automation with minimal reliance on manual or third-party data entry. The ideal state also includes the expanded ability to digitally capture data directly from patients. This lifecycle will require data to be encoded to universal standards in common formats (for example, FHIR data model and LOINC® terminology), which allows secure storage and transmission where required. This transformation to enabling usable and timely data from multiple sources as envisioned in a learning health system will support many use cases including quality measurement and patient care (Figure 6).

The complete uptake of evolving exchange standards (currently FHIR) across all EHR data captured in all healthcare settings will optimize data availability, standardization, and use. Other critical data (all-payer claims, patient-reported outcomes [PROs], and patient-generated health data [PGHD]) will similarly be standardized for interoperability. Data will move instantaneously across the silos in which they are captured and in formats that allow immediate analysis and appropriate application of information to solve emerging problems effectively. Patients can access personalized quality information to guide decision-making, care goals, and provider choice.

Figure 6. Healthcare data lifecycle*. This lifecycle describes the cyclical progression of patient data in the health care ecosystem to achieve continued feedback for and improvement in patient care. The lifecycle is comprised of five steps: 1) capture all data required for dQMs, 2) use a standardized data model, 3) share the data through an API, 4) analyze the data (for example, for quality measure calculation), and 5) interpret and apply the data to support multiple uses not limited to quality measurement. Below this cycle are the key abilities in this digital ecosystem necessary for each step of the lifecycle to achieve this vision.*



Eventually, evolving interoperability standards will make different types of data captured in various settings and for varied purposes available. These data can be merged and analyzed for quality signals and inform research, clinical guidelines, and clinical decision support, and allow for dQMs to represent more complex clinical concepts. Providers can access quality information in near real-time to adapt and improve patient care. Clinical workflow changes for the sole purpose of measurement will be minimal. Workflows will be further aligned to facilitate rapid-cycle feedback and continuous improvement because quality measurement data will largely be captured through care delivery and routine administrative processes.

CMS and others running measure calculations (for example, data aggregators) could administer automated validation protocols against stored or transmitted data to assess data completeness, formatting, and erroneous values. Additional validation protocols can challenge and score the validity of inferences drawn from those data for individuals or populations.

What We Will Achieve

Advance data standardization, transmissibility, and use of digital data

CMS will focus on advancing the standardization of digital data from EHRs to support dQMs that combine EHR data with other digital data sources, such as claims and PGHD. Over the past decade the Department of Health and Human Services (HHS) enacted regulations for standard encoding of data and for data transmission. The

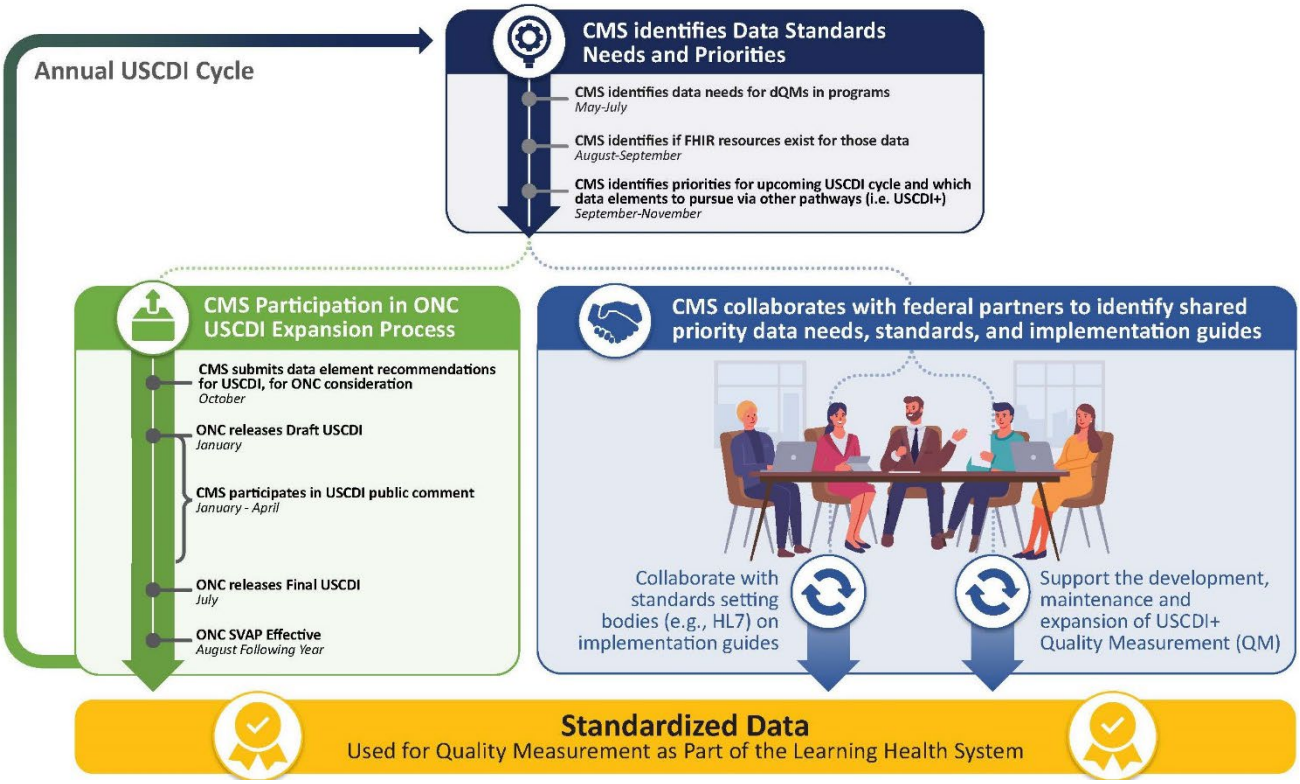
most recent requirements finalized in the ONC 21st Century Cures Act final rule specify certification criterion for certified health IT that requires the use of FHIR Release 4 and several other implementation specifications.[3] Health IT certified to this criterion will offer single patient and multiple patient services that can be accessed by third party applications. This regulation requires health IT developers to update their certified health IT to support FHIR-based APIs that exchange USCDI version 1 data using the US Core IG by December 31, 2022, and exchange of all electronic health information in any computable format by August 2023. The stated goal of the USCDI, which was based on and replaces the Common Clinical Data Set, is to set a foundation for broader sharing of standardized electronic health information to support patient care by requiring providers to use a standardized set of health data classes and constituent data elements for nationwide interoperability. The USCDI defines the data classes and elements, as well as any applicable terminology standards that must be made interoperable, or sharable with patients, providers, and with CMS. The US Core IG further contextualizes the data and specifies the format. These data can be harnessed for measurement both to focus the stakeholder community on advancing sets of data agreed to be important for health care, and to reduce the burden of measurement by using data elements for measurement already required to be made available in FHIR standards. By aligning technology requirements for payers, healthcare providers, and health IT developers, HHS can advance an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

ONC developed the USCDI versions 1 and 2 and continues to release yearly expanded versions based on broad stakeholder input. The USCDI includes some of the foundational data elements necessary for measurement based on EHR data, such as laboratory results, encounter information, patient demographic information, and social determinants of health (SDOH) information.[13] Recognizing that the USCDI will not fully meet unique agency or use case-specific data systems and requirements, ONC created the USCDI+[6] initiative, which will support additional datasets or extensions to the USCDI, beginning with the Centers for Disease Control and Prevention (CDC) and CMS use cases of public health and quality measurement. In order to support CMS's requirements for a comprehensive set of data elements that will be used for future dQM reporting, CMS initiated an exercise (prior to the start of USCDI+) to compile the data elements required for electronic clinical quality measure (eCQM) reporting and invited input on whether they were commonly used by one or more federal partners. This work supported the initial investigation phase for the USCDI+ Quality Measurement (QM) use case. Partners from Agency for Healthcare Research and Quality (AHRQ), CDC, Health Resources and Services Administration (HRSA), Substance Abuse and Mental Health Services Administration (SAMHSA), and the Department of Veterans Affairs (VA) contributed to identifying priority data needs for quality measurement with the overall goals of achieving alignment of data standards and priorities. This work could serve as a model for other data standardization use cases supported by the USCDI+.

CMS will continue to collaborate with ONC and align data used in measurement with the USCDI and USCDI+ to the greatest extent possible. In parallel, CMS will also continue to collaborate and engage with HL7 to advance FHIR implementation guides. The ultimate goal is to align EHR data used for measurement with a single set of interoperability requirements to minimize compliance burden for providers and aggregators. At a minimum, the USCDI should form the core set of standardized data requirements for interoperability from which specific use cases can be built. Using structured and transparent processes (Figure 7) and in close collaboration with ONC and federal partners, CMS will continue to engage in data standardization activities, including the expansion of the USCDI and USCDI+ to meet foundational needs for quality measurement and other use cases,

such as public health surveillance and research. As ONC further defines the process and scope for USCDI+, CMS aims to continue collaborating with federal agencies and others as appropriate and leverage this additional opportunity to further align data standards for dQM use. We also recognize the importance of considering how implementation guides used across quality measurement and other use cases work together to support a learning health system. For example, Clinical Practice Guidelines Implementation Guide connects computable guidelines, clinical decision support, quality reporting, and case reporting. CMS is collaborating closely with federal partners to align where possible.

Figure 7. Pathways to advance data standardization. *CMS will identify data priorities for dQM and engage in the standardization processes related to the USCDI expansion, USCDI+, and implementation guide development/expansion that support EHR data availability and standardization for quality measurement.*



CMS will continue to consider and collaborate with ONC on the policy levers available (for example, CMS rulemaking, ONC Standards Version Advancement Process [SVAP], ONC Certification criteria specific to quality measure reporting) to advance implementation of these national data standards. Additionally, CMS will consider additional measurement requirements that may be necessary. One important example is that the USCDI and USCDI+ will focus on interoperability of EHR data but may not include other data sources needed for a complete dQM portfolio. CMS will continue to collaborate on the maintenance of additional standards that meet quality measurement needs, namely the HL7 Implementation Guides (for example, Quality Improvement [QI] Core Implementation Guide) and value set standardization efforts that organize the specific terminologies and codes that define clinical concepts. The QI Core IG is a derivative of the US Core IG (ONC interoperability standard) and provides more complete details for the quality improvement/quality

measurement use case. CMS will continue to align measurement requirements and standards with ONC and other federal requirements to ensure simplicity for providers.

CMS may also develop and deploy an interoperability measure to test provider success of exposing data necessary for interoperability and measurement (USCDI, USCDI+, and supplemental standards) against an established and standardized target. This potential measure could directly assess compliance with the ONC FHIR API data sharing requirements and ensure providers are able to transmit data needed for measurement using FHIR resources to advance measurement success. CMS, other payers, and providers could use this "measure of interoperability" to assess: 1) the appropriate functionality of the provider FHIR API by executing queries for important data required by ONC and CMS (in FHIR standards), 2) the proportion of successful queries, and 3) the quality and completeness of data retrieved by the queries compared to an expected gold standard. Measure performance will demonstrate the degree to which each provider can transmit data documented at the point of care from the native EHR to an external authorized entity upon request and allow CMS to test additional measurement data elements beyond the USCDI over time.

To achieve success, CMS must work to align current measures with required or developed data standards (USCDI, USCDI+, supplemental standards). CMS will also consider how to exercise policy discipline to ensure future program measurement requirements align with what is available based on these standards, while at the same time continuing to advance standards. Decisions regarding inclusion of EHR data in new measures should begin with the question, "Are the data elements for EHR data required by the measure specifications represented in the USCDI and US Core IG or USCDI+ and QI Core IG?" If not, "Is it appropriate to include new data elements into these standards based on the importance of the measure?" This policy discipline will reduce burden on providers and EHR vendors. This alignment will require a greater degree of collaboration and coordination among agencies. Seamless coordination among ONC, CMS, and standard-setting bodies (for example, HL7) is critical to update standards and requirements in a transparent and timely fashion.

Accelerate digital capture and standardization of new data that are critical to advance quality measurement

CMS will work to innovate and broaden the digital data used across the quality measurement enterprise beyond the clinical EHR and Medicare claims. Digital data used for measurement can expand beyond data captured in traditional clinical settings and EHRs and may sit outside the scope of USCDI and USCDI+, but standards for these types of data are still important for interoperability, patient care, and quality measurement. For example, standards for digital data captured by providers outside of traditional clinical EHRs, such as administrative and business operations data, and SDOH data, should also be expanded. The COVID-19 pandemic has shown the need to track SDOH and race/ethnicity data to examine the degree to which there continue to be inequities in care. It has become increasingly clear that standardized access to operational information such as bed, ventilator, and staff capacity is needed. These business operations data are universally captured and stored as digital information but lack the standardization to make data readily accessible and interoperable. Additionally, measures calculated from merged administrative claims and EHR data require sharing or reporting of both types of data by providers if such measures are to expand beyond the Medicare beneficiary population (to include privately insured and uninsured patients), and to include patients' documented comorbidities within risk adjustment models where appropriate. Some of these data may sit within Certified EHRs regulated by ONC, but these data may also be derived from other sources.

There are also aspirational data sources that are not yet sufficiently mature in digital formats but have been identified by CMS as critical for measurement and care quality. For example, PRO data have been used in performance measurement in limited circumstances and have not yet been fully adopted by CMS and others but are increasingly a focus for quality measurement (for example, the Comprehensive Care for Joint Replacement Program has incentivized hospital submission of PRO data for PRO-PM development). Post-acute care (PAC) assessments are now standardized through the requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014,[15] as are data collected within some CMS programs such as the End-stage Renal Disease Quality Incentive Program[16] through CROWNWeb. While these data are consistently captured within specific settings, they are not yet fully interoperable across other provider settings. Similarly, the modernization of systems and procedures used to capture patient experience survey data, and the development of standards for these data (for example, through collaboration with HL7 on implementation guides), should continue to advance. Technology affords many opportunities to improve response rates and thereby the validity of these data through smart phone applications or patient portals, among others. Further, addressing systemic inequity within the healthcare system also requires accurate and reliable data about race, ethnicity, and SDOH. Progress on USCDI standards for some of these data concepts (including SDOH Problems/Health Concerns, SDOH Interventions, Gender Identity, and Sexual Orientation) have been made and the HL7 Gravity Project[17] continues to be a steward for SDOH data standardization advancement. However, these data are often captured outside of the EHR in the form of surveys completed on paper by patients or assessed outside of the healthcare delivery system altogether through state and local agencies or by social service non-profit groups, and therefore continued standardization and interoperability advancement is critical.

To address all these important data standardization gaps, CMS will encourage innovation in the use of technology to capture these data and collaborate with HL7 in standards advancement to represent the data. For these data to be interoperable and usable, requirements for expressing the data in standards, exposing via standards-based APIs, and incentivizing technologies that innovate data capture and interoperability will be critical. Ensuring all data are expressed in standards and can be exposed via standards-based APIs allows for use of data for measurement among other use cases. It also allows for flexibility in reporting data for measurement. Based on the data type, reporting can be done by providers or aggregators reporting on behalf of providers, by vendors reporting survey-based measures, or by CMS aggregating data from multiple sources for complex measurement. Because many of these data of interest may be captured outside of traditional EHRs, CMS may consider if supplemental requirements described above may be necessary for these digital data.

As CMS works to advance digital data capture and interoperability, it is important to recognize the variation in readiness for data standardization and technology uptake across different healthcare settings. For example, hospitals and clinicians previously required to utilize Certified EHRs for measure reporting may more easily uptake interoperability capabilities compared to other settings. It will be important to consider the needs of providers who were not included in federal investments in EHR implementation; CMS will continue to collaborate and support providers and care settings during this transition. CMS envisions the transition to digital measurement will be incremental based on readiness of providers and aims to begin the transition with FHIR eCQM reporting in appropriate reporting programs as the first step to digital quality measurement.

Appendix C provides examples of data types and digital strategy progress, and suggestions for next steps to advance digitization.

Advance tools and processes to validate data used in measurement

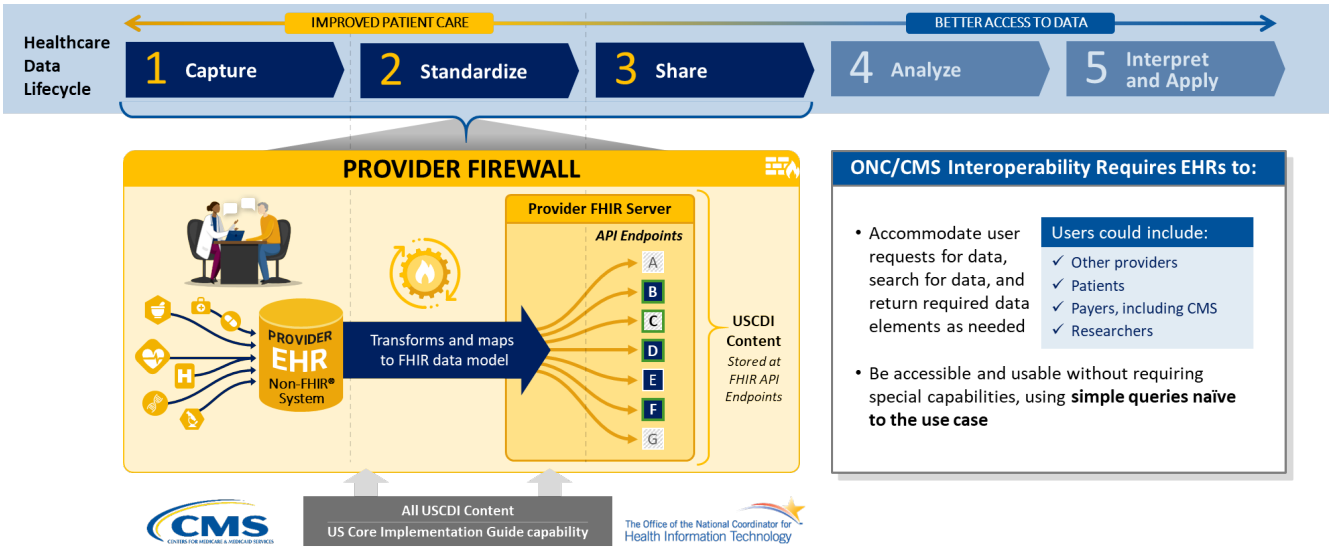
CMS, along with vendors and providers, will consider how to develop and deploy advanced tools and methods for data quality and completeness validation. One of the most significant barriers to expanding dQMs is appropriate concern about data quality in terms of validity, accurate assessment of the underlying clinical concept, and the reliability of data within and among those who capture information. There will always be error in data collected through human interaction or through subjective human observations and inference. Although two clinicians might observe different blood pressure values from the same patient, they will both agree that what they are measuring is a blood pressure that is an intermediate biomarker for a variety of health outcomes. They might also agree that it is not appropriate to draw extensive conclusions from a single assessment of blood pressure, but that a pattern can be inferred from multiple abnormal readings. Further, they might concur that a period of time with persistently abnormal blood pressure followed by the onset of acute kidney injury, and worsening of chronic kidney disease, may indicate correlation and even causation. There are many layers to validity in this example including the accuracy of a single data point, the inference drawn from multiple values, and the deduction of correlation or causation from two biologically and temporally related clinical patterns. Each layer plays a role in our understanding of and confidence in of quality measurement and assessment of performance.

Mapping data to nationally supported standards is an important initial step in confirming the association between a data value and a clinical concept. However, additional validation and auditing is necessary to ensure accountability for truthfulness, and adherence to standards and requirements, as well as to interrogate and revisit assumptions and conclusions made about data values, patterns, and correlations. CMS and other agencies currently conduct audits of digital data; examples include the National Committee for Quality Assurance (NCQA) audit system,[18] CMS claims, and eCQM audit systems.[19] These auditing functions include checks for data completeness and data accuracy, confirmation of proper data formatting and alignment with standards, and appropriate data cleaning. CMS and other entities, such as Health Information Exchange Organizations (HIEOs) and other aggregators, should continue to evolve their audit systems and processes, and work towards automation wherever possible. Similarly, providers, aggregators, and others running measure calculations should use automated validation processes for data cleaning and processing. Measure developers can also take advantage of automated validation systems to demonstrate measure score construct validity. As researchers and subject matter experts develop new technological and analytical advancements, such as natural language processing (NLP) and artificial intelligence (AI), they can support the evolution of data validation and auditing. These techniques can also be applied to validating observed patterns in data and inferences or conclusions drawn from associations. Quality measures should increasingly rely on data patterns rather than on individual data values to derive meaning and assess performance as this process protects against extensive reliance on a single data point and the drawing and amplifying of erroneous conclusions.

Advance data transmission using FHIR APIs in the near term

The potential applications of the updated ONC Health IT certification requirements[3] expand well beyond quality measurement. Secure, rapid, and standardized data sharing can transform the way health care is delivered. There is no doubt we have reached a critical milestone. CMS's Division of Electronic and Clinical Quality (DECQ) is preparing for eCQM reporting via standards based FHIR APIs, based on the ONC requirements (Figure 8), as the first step in the dQM transition. Ideally, the use of standards-based APIs to exchange any data used for measurement, even if outside the provider EHR, will be supported. For example, the collection and exchange of survey data by vendors or PGHD via patient portals will be done electronically, in standard formats and exposed via APIs. Capitalizing on standardized data and standards-based APIs advances interoperability. It ensures data used for measurement can also be available to patients and used for other use cases including quality improvement efforts, clinical decision support, research, and public health to contribute to a learning health system. CMS aims to leverage interoperability requirements to reduce burden of quality measure reporting and is committed to exploring all pathways for data flow that reduce provider reporting burden.

Figure 8. Provider FHIR API implementation. *Each provider EHR must transform patient data elements specified in the USCDI to a standardized FHIR data model. These data elements will be stored in the provider's FHIR server within API endpoints. Authorized users (other providers, patients, payers, and researchers) can make data requests to the provider EHR at these endpoints, and the provider EHR will return the necessary data elements. Within the healthcare data lifecycle, this requirement is relevant to achieving data capture, standardization, and sharing.*

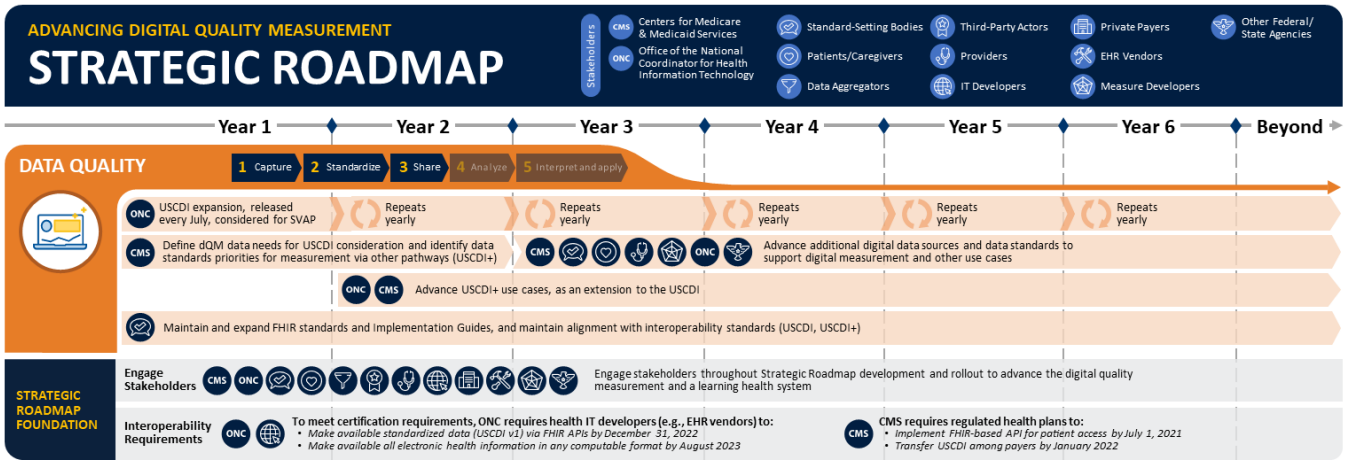


CMS anticipates that provider efforts, along with those of their EHR vendors, to adopt updated interoperability requirements will be met with variable success over the coming years and we are cognizant of the costs associated with such infrastructure investments as well as the need to ensure responsible stewardship and security of these data. CMS will consider deploying an interoperability measure to allow providers and EHR vendors to test their success against an established and standardized target, as described above. This potential new measure will assess data compliance, data quality, and provide specific feedback to providers on the FHIR API functionality, as required by ONC interoperability requirements and specific digital measurement needs.

This type of measure and tool could complement ONC certification testing processes and test real-world application of FHIR APIs for quality measurement. Unlike past health IT and interoperability measures that only require attestation, this measure will require demonstration of API functionality to support measurement. This type of measure aligns with the Meaningful Measures priority "Seamless Communication"[7] and the National Quality Forum (NQF) priority of development of performance measures in effective communication and care coordination, including measures focused on health IT, to help foster better communication between providers to improve patient care. [20,21]

At the core of quality care and informative and reliable measurement is access to high quality, usable, and valid data. To effectively advance data quality and achieve the goals laid out above, coordinated efforts are necessary among key stakeholders. CMS will collaborate directly with ONC and HL7 and standard-setting bodies to advance and expand data standards for interoperability. It will be critical to engage providers, vendors, and measure developers in the processes and decision-making. Figure 9 provides an overview of the key milestones and Appendix D provides a more detailed list of key actors and potential actions to advance digital quality.

Figure 9. Overview of domain 1. *This figure shows the milestones for achieving data quality improvement. See the Conclusion for how these milestones and the other domain milestones integrate to support reaching CMS's goal of digital quality measurement.*



DOMAIN 2: Advance Technology

Our Approach

CMS dQMs should be designed to lower the burden of quality measurement, foster innovation, and enable broader utilization of quality measurement resources. Current eCQM frameworks and reporting workflows require providers and their health IT vendors to dedicate substantial time and resources to implement and maintain bespoke software solutions and data mappings to support each measure. To transition to more agile, less burdensome quality measurement, we focus on two strategies:

1. **Explore the development of measure calculation tools (MCTs) that are FHIR-based, reliable, and implementable across multiple platforms**
2. **Support and certify MCTs developed by others**

Ideal Future State – Organizing Goals

In the future state, we envision CMS dQMs could be self-contained software packages, or MCTs. Each MCT would perform three functions: 1) obtain data via automated queries from digital data sources needed for measurement (for example, from standard FHIR APIs) and format it for analysis; 2) calculate the measure score according to measure logic; and 3) and generate required output (Figure 10).

EHR data needed for the measure would be made available by the provider FHIR APIs as mandated by ONC. As shown previously in Figure 8, the FHIR APIs would serve as gateways to specific data elements and would be naïve to the use case of quality measurement. Data would then be exchanged and used for quality measurement (or other use cases) with the MCTs but the data source API would not be expected to execute measure logic or perform any logical analyses for any given use case.

The MCTs will be designed to be compatible with standard IT infrastructures and query any EHR system that has a FHIR API compliant with ONC's certification requirements. This approach contrasts to the currently structured CMS eCQM software that vendors and providers develop as non-standard solutions deeply embedded in proprietary EHR code stacks. The MCT, in contrast, will not need to be integrated into the vendor's EHR. It will be testable as a self-contained module separate from the EHR, including solutions developed by the same vendor as the EHR. As a result, it can be updated and recertified by the developer and measure steward on its own schedule without a complete recertification or update and deployment of the EHR system.

CMS envisions each MCT as a self-contained software package that is designed to work as part of a service-oriented architecture. CMS and other stakeholders could produce these tested, certified, and reliable MCTs. Publicly funded and privately developed MCTs would share a core set of tooling (such as the Clinical Quality Language [CQL] engine), and updates and improvements to this open-source core will therefore easily propagate across MCTs. This approach will facilitate more rapid advances in measure technology; for example, MCT components may eventually include software for NLP of EHR data as we advance this science for measurement.

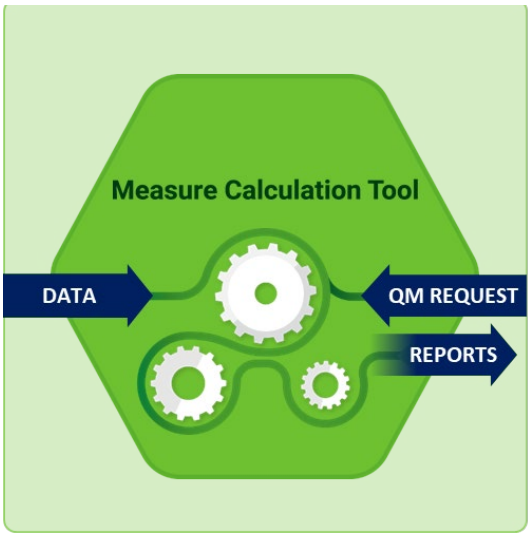


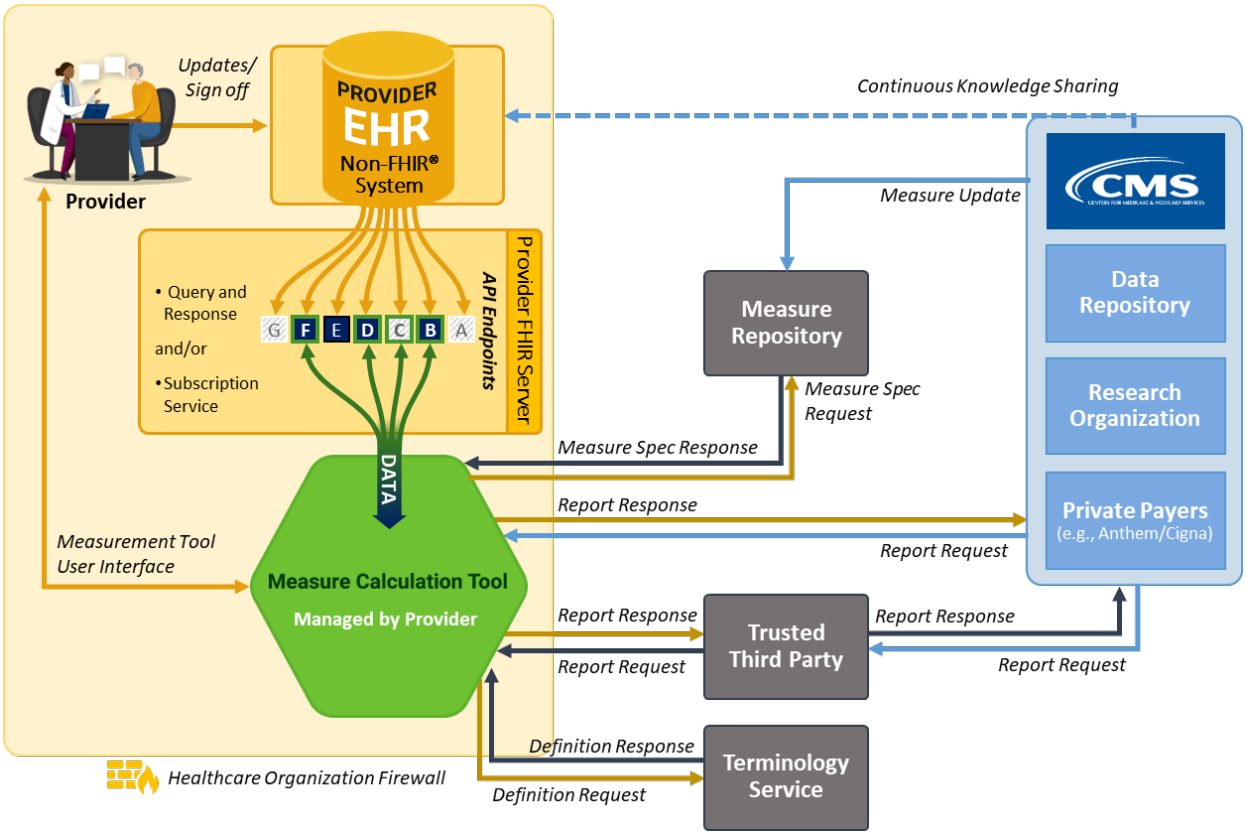
Figure 10. Measure calculation tool (MCT) inputs and outputs. *An MCT is an open-core software package that will leverage interoperability requirements to generate measure reports with limited additional provider burden. Each measure's MCT receives necessary data elements by querying provider EHRs via FHIR APIs or gathering data from other electronic sources. After receiving the data, the MCT formats the data for analysis and calculates a measure score as specified by the measure logic. The MCT then creates a measure report from this score, which can be provided to interested stakeholders as needed. Importantly, an MCT could be implemented in different settings (by CMS, providers' EHRs, or third-party vendors).*

What We Will Achieve

Explore the development of MCTs that are FHIR-based, reliable, and implementable across multiple platforms

CMS will explore the development of MCTs as the end-to-end solution (measure development through reporting and accountability) that minimizes burden and scales to support digital quality measurement. The overall data capture and reporting process could be designed similar to the CDC's Making EHR Data More Available for Research and Public Health (MedMorph) project, which seeks to facilitate effective and rapid public health action while ensuring that EHR data exchange remains reliable and adaptable and minimizes burden. MedMorph relies on EHR data through a FHIR API as the data source, as well as a knowledge artifact repository that houses the most current clinical guideline logic, and a backend services application that facilitates data queries and transmissions to and from public health authorities and research organizations. For dQM reporting, the MCTs could request data across systems in a standardized manner (consistent with ONC's final rule),[3] respecting the required functionality of the FHIR APIs, where applicable, without imposing additional capability requirements on existing data source system(s) and based on open-source projects (open-core) (Figure 11). MCTs would ideally be installable software that includes all the tooling needed to perform their function (collect data, calculate measure, and report results) produced as a deliverable of the measure development process. Much of the tooling would be common across all MCTs for FHIR-specified data elements, but other features such as the specific data queries and logic will vary across MCTs for different measures. Measure developers would also update the MCTs, negating the need for providers to maintain versioning within their EHRs, as in the current state.

Figure 11. Overview of MCTs installed and hosted in the provider's EHR firewall. *The provider EHR (in dark yellow, cylinder shape) would transform patient data elements specified in the USCDI or USCDI+ to a standardized FHIR data model. These data elements will be stored in the provider's FHIR server with API endpoints, ready to be delivered when requested to an MCT, which is maintained by an outside party. When a data client (in blue) or measure repository, trusted third party, or terminology services (in grey) sends a measure report or definition request to the MCT (in green) that sits within the provider's firewall (in the light-yellow rectangle) but outside the EHR, the MCT queries for the necessary data elements. After receiving the data, the MCT further formats the data for analysis and calculates a measure score as specified by the measure logic. This score is delivered to the requesting data client and is available to all approved data clients. Continuous knowledge sharing will be promoted through the transmission of data between the data clients and the provider EHR.*



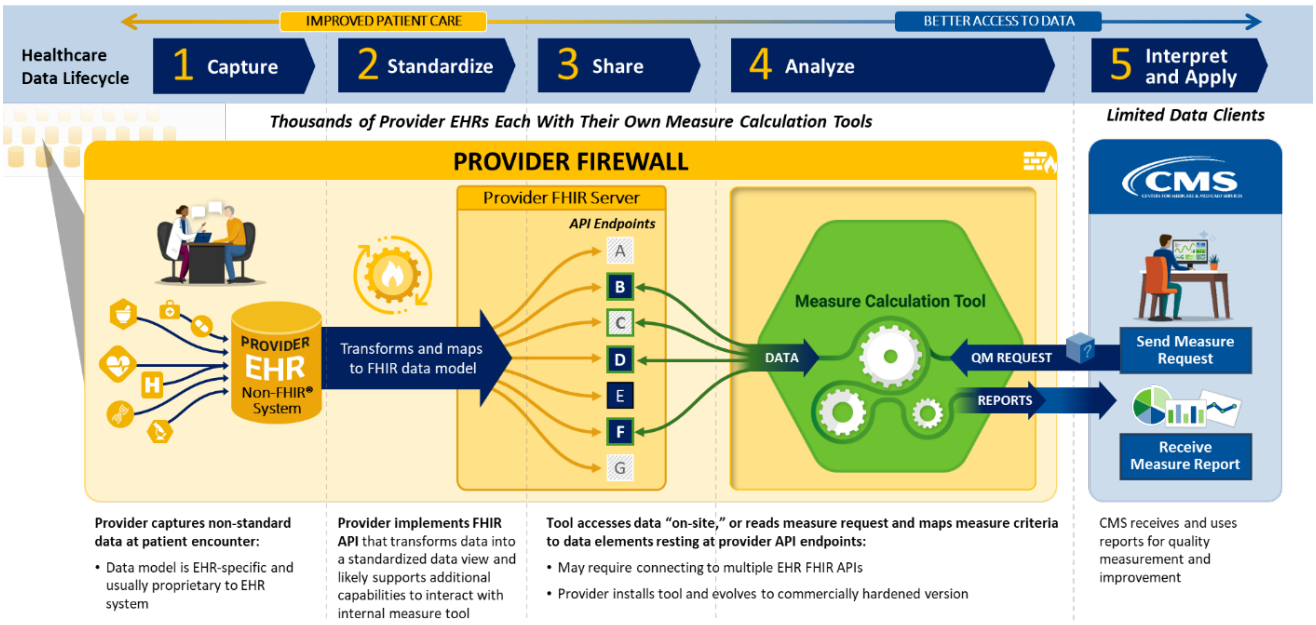
At its core, the MCT would be a measure calculation software package, similar to measure calculation packages used by CMS to produce annual administrative claims-based measure results. However, this new approach to design will extend its capabilities beyond just quality measure calculation. Components of the MCT, such as the steps to query, define cohorts, and complete analyses to calculate the measure score and the report generation and formatting, will be resources to the broader quality measurement enterprise that could be:

- Used as a modular application consistent with a service-oriented architecture and enable providers to standardize and transmit data for measurement purposes with a measure repository, trust third parties, terminology services, CMS, private payers, and others;
- Leveraged by providers, data aggregators, health plans, CMS, and others to generate rapid-cycle feedback to providers; and
- Shared and repurposed by stakeholders for various uses including data aggregation, quality improvement, public health, and research.

To ensure MCTs calculate measure scores accurately and allow for flexibility in how they are coded, CMS will move to a test-case based approach with a complementary, robust set of hundreds of test cases and standard procedures for testing and versioning. This will allow CMS, other developers, providers, data aggregators, and others to ensure that MCTs produce accurate and reliable results while also allowing for flexibility in how they are implemented. CMS, quality measure developers, and health IT developers would test measures using real-world data sources to demonstrate that the MCTs accurately retrieve FHIR-formatted resources via FHIR APIs. This testing will ensure the MCTs work across various platforms and include the capabilities outlined above. Further, CMS will incorporate user experiences and augment test cases based on real-world feedback from each tool's use in the field. Over time this performance-based assessment will allow for the testing of expanded strategies to use data from EHRs and other sources, including incorporating NLP and other advanced analytic approaches, and provide measure and health IT developers with maximum flexibility.

This tooling would allow CMS to make its MCTs available for implementation by individual providers (such as health systems) and/or data aggregators or other external entities (for example, HIEOs, quality measurement contractors). This approach would allow providers to select the option that is best suited to their needs, promote market innovation, and support alignment of measurement with multiple use cases such as research and clinical decision support. Figure 12 shows an MCT if implemented by a provider such as a health system. Appendix E depicts the functions of the MCTs if they were implemented by CMS (Figure E1) or by a data aggregator (Figure E2).

Figure 12. Providers develop and implement their own MCTs*. In this scenario, the provider EHR (in yellow) would transform patient data elements specified in the USCDI or USCDI+ to a standardized FHIR data model. These data elements would be stored in the provider's FHIR server within API endpoints, ready to be delivered when requested to an MCT, which is maintained by an outside party. When a data client (in blue) sends a measure report or definition request to the MCT (in green) that sits outside of a provider EHR but within the provider's firewall, the MCT discerns the data needed and queries the FHIR API within a provider's EHR at its endpoints for the necessary data elements. After receiving the data, the MCT further formats the data for analysis and calculates a measure score as specified by the measure logic. This measure score is delivered to the requesting data client and is available to all approved data clients.*



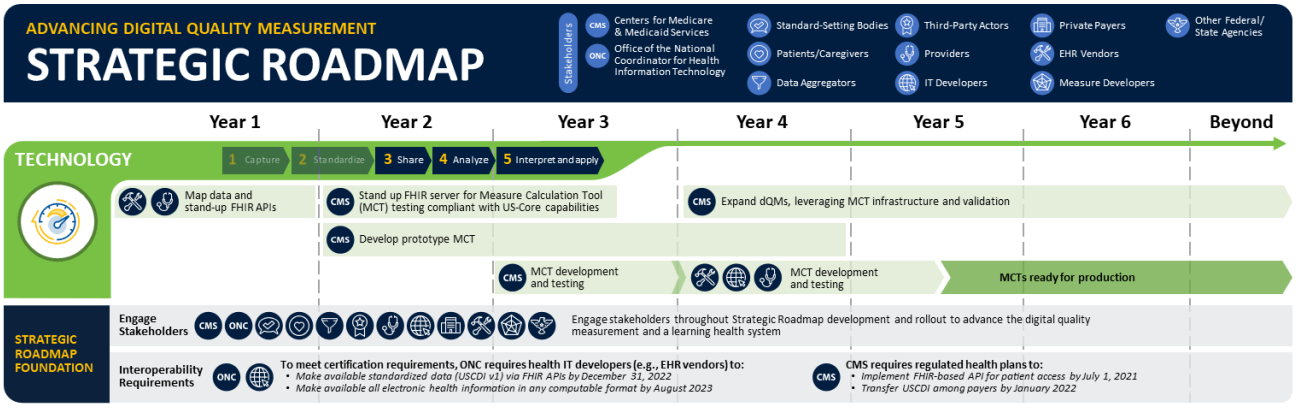
In developing MCTs, CMS would build on its substantial work to date converting measures from the Quality Data Model (QDM) to FHIR. Significant components of the logic and existing open-source tools used to translate and validate the converted measures could be used in the restructured MCTs. Further, CMS will modernize its Measure Authoring Tool (MAT) and test case development tool, Bonnie, replacing them with Measure Authoring Development Integrated Environment (MADiE). MADiE is software that will provide an integrated environment for measure development and testing, which is currently supported by the two separate MAT and Bonnie tools. In modernizing its tooling, CMS would consider how the tooling could support generation of measure logic that can be certified as compatible with an open-core toolset as well as measure development consistent with MCT design constraints and data sources. Testing and validation of the MCTs would incorporate FHIR API queries of EHR data to establish measure usability and provide the robust set of test cases needed for CMS, providers, and others to have confidence in the measure results produced by the MCTs.

Support and certify MCTs developed by others

CMS will continue to use measures developed by others in our quality reporting and value-based payment programs. To support entities such as clinical registries, data aggregators, and vendors that want to produce their own MCTs to satisfy CMS reporting requirements, CMS will share tooling for development and establish a maintenance and certification process for other stakeholders' MCTs. This process would be transparent so that all entities involved understand how data are processed, validated, aggregated, and analyzed, and would be complementary to the ONC FHIR API certification. CMS would develop standard procedures for testing and versioning to allow those groups that choose to develop an MCT to ensure that their product consistently produces accurate and reliable results. This approach is analogous to but broader than the current eCQM annual updates process as it would affect all of CMS's reporting programs.

CMS will expand the capabilities of measurement by capitalizing on advances in interoperability and exploring MCTs as an end-to-end solution. The use of MCTs could reduce provider burden to maintain and implement measures while supporting more agile measure development. Health IT vendors, providers, aggregators, and others would actively participate in the development, testing, and use of the MCTs. CMS would work to develop a certification process for MCTs, and promote their widespread use by HIEOs, clinical registries, providers, and others. Figure 13 provides an overview of the key milestones, and Appendix D provides a detailed list of key actors and potential actions.

Figure 13. Overview of domain 2*. This figure shows the milestones for advancing technology to achieve digital quality measurement. See the Conclusion for how these milestones and the other domain milestones integrate to support reaching CMS's goal of digital quality measurement.*



DOMAIN 3: Optimize Data Aggregation

Our Approach

Data aggregators currently play a vital role in the acquisition, processing, transmission, analysis, and application of digital health information. They are entities that combine, map, validate, and align data by defined standards from multiple sources to produce larger datasets, enable data centralization, minimize data fragmentation, and buoy data interoperability. The technology and system solutions that CMS adopts should utilize their expertise, capabilities, and their unique relationships with providers, payers, and the regional and state public health infrastructures to aggregate data for measurement and other uses. CMS will assess and expand data aggregation functionalities and processes to continue to support data aggregation for nation-wide quality measurement. Further defining the role of data aggregators in the quality measurement enterprise can minimize provider burden and enable complex, independent quality assessments and more valid measurement when complete patient data (data collected across multiple providers and from multiple settings) are required. To effectively capitalize on their expertise and capabilities, we focus on one initial strategy:

1. **Define and optimize the role of data aggregators to support the digital quality measurement ecosystem**

Ideal Future State – Organizing Goals

Aggregation of digital data is critical for measures that depend on information from multiple providers or sources, such as risk-adjusted outcome measures or measures that require standardization for calculation of results. However, a solution that requires CMS to serve as the only data aggregator is neither cost effective nor desirable. In the future state, data aggregators will continue to play a central role in supporting measure calculation via the MCTs, in addition to unique services provided such as repurposing measure specifications and results to create quality improvement tools for improving public health, patient experience, and outcomes. CMS will continue to serve as a data aggregator, particularly for nationally risk-adjusted measures. Advances in data quality and technology, discussed above, will create additional opportunities for data access for these aggregators. Some states and regions might also have emergent health needs that require data aggregation and analysis. Therefore, utilization of, alignment, and synergy with key data aggregators can augment the positive impact of CMS's digital solutions and can serve as empowered partners to promote a learning health system.

Many data aggregators operating today serve their clients by absorbing the burden of multi-source data cleaning, processing, validation, analysis, and quality reporting. As a result, their work leads to more

comprehensive and accurate datasets that can continue to be used for quality measurement, attribution, risk adjustment, and other activities. The location of these data aggregators in the broader healthcare ecosystem, where they serve as a middle tier, is critical as they are ideally positioned to address many of the challenges of the model for leveraging FHIR to acquire data for measurement and feedback to providers for quality improvement.

Currently data aggregators respond to the needs of their clients, which include health systems, payers, and regulators, and some participate in federal quality reporting programs. However, this role still varies across aggregators and CMS will explore whether additional guidance would further align and enhance these activities. Sufficient guidance and requirements set by CMS/federal agencies that enables them to fully participate in federal programs will facilitate better alignment and integration of quality measures across payers and federal, state, and local regulators. If the capabilities of data aggregators were further leveraged in the future, it could result in the following capabilities:

- Centralize data to be used for various purposes, such as measurement, national disease and outbreak surveillance, cross-setting care coordination, research, and continuous quality improvement;
- Minimize data fragmentation, by matching patients with their records across sources;
- More successfully apply risk adjustment and attribution to measures calculated based on the most comprehensive and timely data available;
- Increase data sharing transparency to patients, through robust auditing and reporting; and
- Efficiently acquire data necessary for patient-centered measurement through a minimal number of queries to a limited set of more comprehensive FHIR data repositories.

What We Will Achieve

Define and optimize the role of data aggregators to support the digital quality measurement ecosystem

CMS will engage with data aggregators to understand their reach and scope and to identify opportunities for enhanced processes in the digital quality measurement ecosystem. There are a variety of organizations that currently serve in the data aggregator role. The healthcare aggregator ecosystem can be defined in three categories, with data flowing between data collectors and aggregators and established feedback loops (Figure 14):

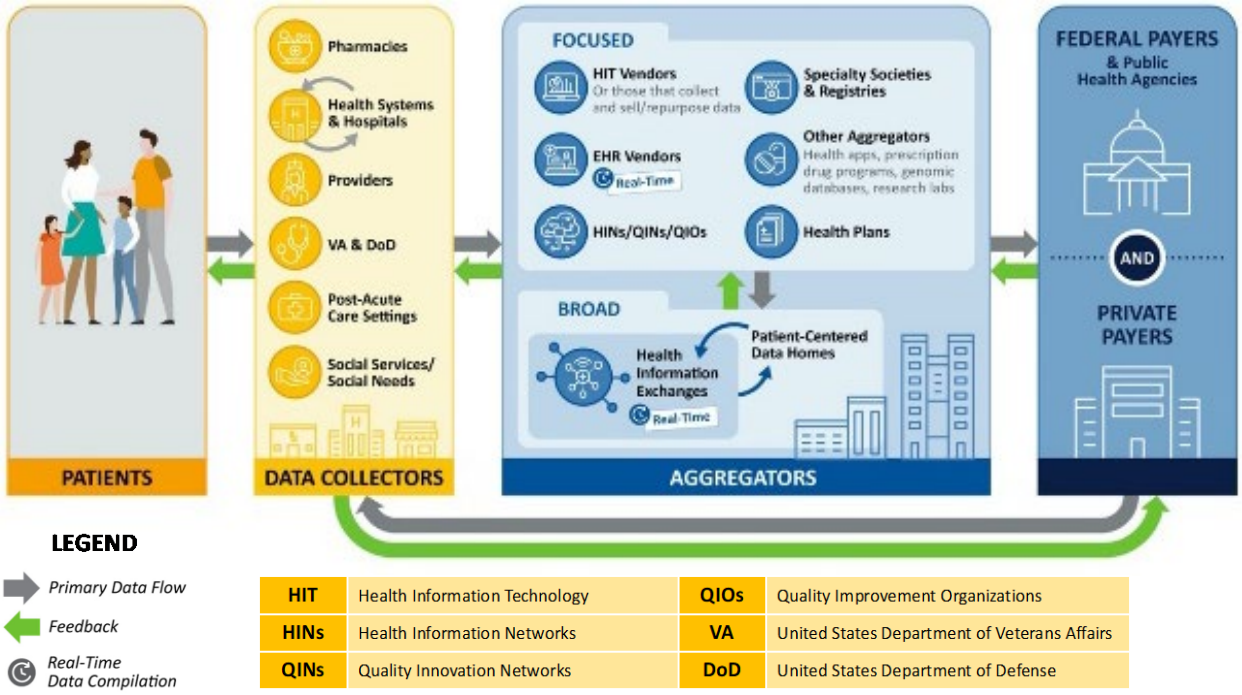
- *Data collectors* (for example, hospitals, health systems, social services agencies, pharmacies) aggregate data for their own patients or clients, and across their own affiliated organizations. Data collectors are frequently the original source of data that are used for quality signals within their setting or silo. There are often limitations in ability to access information captured beyond their own "walls" as well as in ability to contextualize their own experience relative to peers or other related settings.
- *Focused aggregators* collect and combine data from primary data collectors for a set of narrow or specific purposes, often related to client needs. Examples are those focused on specific use cases such as specialty societies with registries targeting specific disease states or clinical specialties, and entities that aggregate specific types of data such as EHR vendors aggregating clinical data from EHR systems

with a focus on healthcare business solutions. These data aggregators often access data from primary data collectors and other data aggregators.

- *Broad aggregators* (for example, HIEOs and CMS) combine data from other data aggregators, across many data sources, and for multiple purposes. The Strategic Health Information Exchange Collaborative, the trade organization for HIEOs, allows for data sharing among HIEOs by establishing Patient-Centered Data Homes and reports that more than 290 million Americans have their health records already aggregated to some extent in an HIEO.[22] Data Sharing Networks allow for sharing of a broad range of data, but function as federated models by indexing information and telling users where complete information is for file retrieval and access, but not storing all complete data in a central place.

Federal and private health plans and payers, including CMS, also serve as important data aggregators, and will continue to do so in the future state. These entities continue to expand the type of data they collect, from administrative claims, EHRs, and PGHD.

Figure 14. Aggregation system for health care. *In this ecosystem, patient health information is collected by data collectors (for example, healthcare providers), who initiate iterative, efficient cycles of patient data submission (shown via grey arrows) to payers and data aggregators, who analyze this data and provide feedback on the submitted data (shown via green arrows) to interested parties. This ecosystem connects patients, providers, data aggregators, and federal agencies to help ensure proper acquisition, processing, transmission, analysis, and application of digital health information. This diagram differentiates between focused aggregators (in blue), who collect and combine data from primary data collectors for a set of narrow or specific purposes, and broad aggregators, who combine data from primary data collectors and other data aggregators, across many data sources, and for multiple purposes. Both serve within this flow of data and feedback that can ultimately lead to more complete, standardized, and usable data.*



Many data aggregators, such as HIEOs and clinical registries, currently support participation under the Merit Based Incentive Payment System (MIPS) as well as Medicare and Medicaid Promoting Interoperability, and some play a role in enabling providers to meet the interoperability requirements set by CMS and ONC by supporting data standardization and normalization. Thus, data aggregators already provide critical infrastructure for data exchange to support care delivery, coordination, and measurement, which CMS may use and expand. To function in this space, data aggregators and providers must continue to define agreements for data sharing, which the ONC TEFCA work supports. It is important to recognize the different types of data aggregators and different services they provide related to timeliness of data aggregation and distribution, scope and sources of data collected, and the resources and tools provided, as these will impact their interactions with CMS. Some of their key functions relevant to quality measurement are to:

- *Provide tools and resources* such as quality improvement tools, clinical decision support, and public health reporting;
- *Clean, validate and process data*, including validation and cleaning of data in real-time or batched (for example, monthly or quarterly), normalizing vocabularies, and delivering cleaned, organized, and multi-sourced data for multiple uses. HIEOs and EHR vendors typically provide the most real-time communication, while other data aggregators tend to batch data communication;
- *Resolve patient identities by* providing robust algorithms and tools to enable appropriate patient record matching for data merges across providers. This function works independently of any specific patient identifier, enabling its continued effectiveness even if a single national patient identifier is never implemented. CMS will continue to monitor and collaborate on activities for patient identification, including work being conducted by the ONC Patient Identity and Matching work group,[23] Project US@ and the Patient ID Now Coalition.[24]
- *Deduplicate data* to resolve instances when the same data (for example, a lab result or medication) are reported more than once because they appear in distinct systems;
- *Decrease FHIR API query load* caused by a substantial increase in internet traffic, which could potentially overwhelm the system. At its core, accessing data via an API is a federated data query to an outside system. Depending on the number of APIs to be queried (tens of thousands if in a local community, millions if nationally), the performance of the entire system could be adversely impacted. For the purposes of the quality measurement, centralized models can reduce query volume;
- *Convert data* to FHIR standards, and terminologies appropriate for USCDI and USCDI+ data. By centralizing this support for providers, variability in mapping decisions could be reduced, as fewer entities will be making mapping decisions;
- *Support credentials and API access security;* data aggregators are already focused on granting and revoking access permissions to sensitive protected health information (PHI); utilizing an application and credentialing process to approve access; and robust audit logging to monitor the use of the data, reducing provider burden; and
- *Submit data* and measure results to federal and private payers on behalf of providers and others for value-based purchasing, direct contracting, and other uses.

CMS will explore what additional guidance and requirements are needed to ensure that data aggregators are equipped to aggregate and report the data required for dQMs. This process could ensure that:

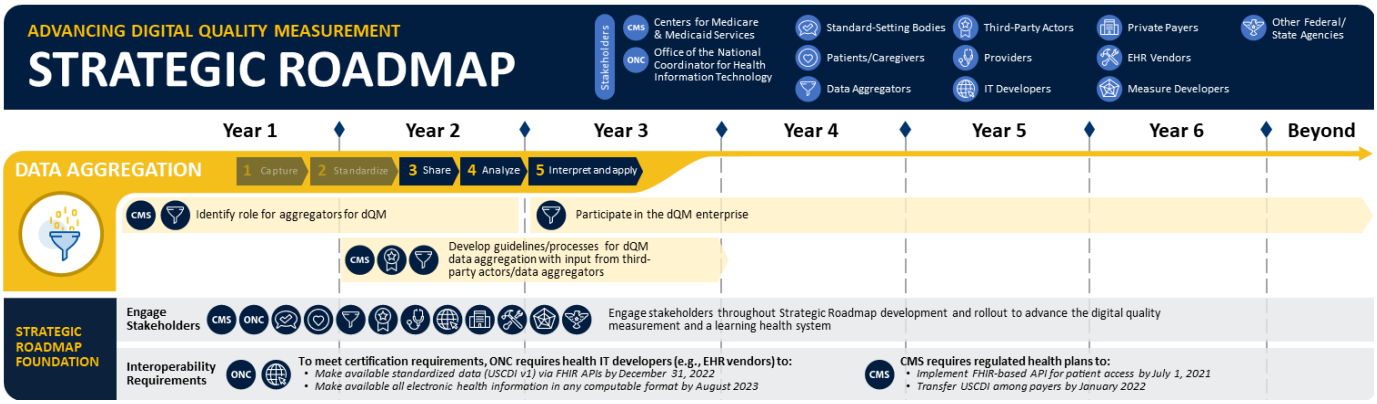
- Aggregators' data systems and procedures are sufficient for reporting quality measures;
- All MCTs are correctly supported and functioning as expected;
- Aggregators demonstrate their capacity for and appropriate function of systems for patient matching, data merging (across silos or sources), data cleaning and deduplication, validation of input files to the MCTs, and the measure output; and
- Patient privacy and the minimum necessary standards for PHI exchange are honored and maintained.

There are several programs that could serve as models for providing guidance and processes to ensure appropriate aggregation steps occur. First, NCQA piloted a data aggregator certification program, the Data Aggregator Validation program,[25] which aims to ease the burden of audits and validation work for health plans and providers. In this pilot program, NCQA tests data coming into data aggregators for completeness, accuracy, and reliability, and ensures that the data transmitted out by data aggregators are in standard formats. CMS also governs processes for approving registries, called Qualified Clinical Data Registries and Qualified Registries, for the MIPS program reporting. CMS requires applicants to demonstrate the steps by which data submissions are verified for accuracy and audited to ensure data completeness and usability. These types of processes can be used as examples as CMS explores additional guidance and requirements for data aggregators in a digital measurement ecosystem.

In parallel to activities and engagement with data aggregators and other third-party actors, CMS will assess the infrastructure and processes in place to continue to serve as a central data aggregator and calculator of nationally risk-adjusted measures. Specifically, CMS will modernize receiving systems to support streamlined processes that will allow for a singular point of data receipt for data aggregation and quality reporting requirements, and modernization of programmatic data receiving systems to leverage opportunities related to digital data.

The use of aggregated data from multiple sources allows for more precise and usable data for measurement, national surveillance, and care coordination, among other opportunities. Defining the role that data aggregators play in the quality measurement enterprise through transparent and clear processes can also help reduce provider burden, while advancing care quality and potentially decreasing cost. To effectively achieve the goals laid out above, coordinated efforts are necessary among key stakeholders. CMS will engage with data aggregators and other third-party actors to provide additional guidance on processes and expectations. Providers, patients, and health IT and EHR vendors should also play a critical role in the process. Figure 15 provides an overview of the key milestones and Appendix D provides a more detailed list of key actors and potential actions.

Figure 15. Overview of domain 3. *This figure shows the milestones for data aggregation. See the Conclusion for how these milestones and the other domain milestones integrate to support reaching CMS's goal of digital quality measurement.*



DOMAIN 4: Enable Measure Alignment

Our Approach

To support digital quality measurement that reduces burden and supports health system-wide learning, quality measures must be aligned across public and private payers and within and across programs, settings, and providers. To further this alignment, we focus on two strategies:

1. **Develop a common dQM portfolio aligned across programs, agencies, and payers**
2. **Accelerate the alignment of data standards and tools across federal agencies, states, and the private sector**

Ideal Future State – Organizing Goals

Ensuring alignment of measures across payers and value-based programs remains a priority for CMS, other federal and state agencies, private payers, providers, and other stakeholders. To date, efforts to develop coordinated measurement strategies have had limited success due to challenges created by disparate data sources, settings of care, and priorities, as measures are still typically program-, agency-, payer-, and setting-specific. In this future state, across settings, payers, programs, and providers, we will use better aligned, patient-centered measure sets that cover the highest priority quality domains and anticipate and assess potential unintended consequences of quality measurement. The quality measurement community already strives for and to some degree has achieved measure alignment via the use of common value sets and software. For example, CMS developed, uses, and maintains open-source software applied across its readmission and admission measures to define the outcome of unplanned admissions, and this open-source software has been adopted by other developers. Further, NQF's endorsement processes evaluate and facilitate measure alignment. However, none of these processes have been adequate to achieve the alignment in measure sets and digital value sets needed to reduce provider measure implementation burden and optimize measurement's support of quality improvement and accountability such that different stakeholders are incentivized toward similar quality improvement targets.

A primary strategy for accelerating progress is to drive consensus on and prioritize achieving interoperability of the digital data most needed for priority quality measures as discussed in the Improve Data Quality domain. Much of the data needed exist in EHRs but may or may not be captured as discreet data enabling ease of reporting, so advancing ONC requirements will support innovations in measurement. For example, we can identify hypertension values in standardized EHR data fields, but we will need more contextual and longitudinal information and possibly new standardized algorithms to

differentiate between mild and more severe hypertension, and to assess rates of disease progression. Setting priorities for data and measurement algorithms will help us advance more quickly and with greater coordination toward implementing the most important measures consistently.

In an ideal future state, measures across public and private quality and value-based payment programs would be highly aligned, providing a coherent and coordinated assessment of health care quality. Aligning and developing FHIR standards and tools for eCQMs and striving toward data element standardization are important first steps toward dQM alignment. CMS will work with public and private initiatives to advance alignment.

What We Will Achieve

Develop a common dQM portfolio aligned across programs, agencies, and payers

A common dQM portfolio requires alignment of: 1) the individual data elements used to build these measure specifications and calculate the measure logic; and 2) measure concepts and specifications including narrative statements, measure logic, and value sets.

Because true alignment of measures cannot be fully successful until we are able to ensure that the underlying data are consistent, CMS will prioritize agreement across a wide set of stakeholders on a standardized portfolio of data elements to be used in dQMs in the private and public sectors, beginning with the USCDI and USCDI+, using the same collaborations and activities leveraged for measure alignment discussed below. This work will be iterative and will focus initially on alignment across CMS programs and other HHS agencies and may expand to the private sector over time. CMS will also continue to focus on the identification of dQMs that assist the healthcare ecosystem achieve improvement in patient outcomes and are aligned across settings, providers, and payers; however, it is likely that measure alignment will follow a different timeline and governance process. The involvement of many stakeholders will be necessary to meet the goal of reducing the current quality measurement challenges resulting from wide variation in the representation and measurement of clinical concepts and definitions. This variation frequently requires unnecessary and duplicative work to manipulate and transform data to meet reporting requirements and can pose validity challenges in measure development endeavors.

To the greatest extent possible, the EHR data needed for this aligned portfolio should be limited to those required for interoperability by ONC. However, we anticipate moving to a common dQM portfolio in the near term will not be fully supported by ONC interoperability requirements, as some necessary data elements will not be required by all measured providers for interoperability. Existing statutory, regulatory, and Certified EHR Technology (CEHRT) requirements and efforts in progress provide a foundation for CMS as well as federal, state, and private partners. For example, some of CMS's quality reporting and payment programs and the agency's Center for Medicare and Medicaid Innovation (the Innovation Center) models require the use of health IT certified by ONC (currently, 2015 Edition CEHRT). These programs include but are not limited to the Medicare and Medicaid Promoting Interoperability Programs, aspects of the Quality Payment Program, and the Primary Care First Model. However, current requirements for data interoperability vary across these and other CMS programs and the Innovation Center models. An early step in developing the portfolio will be to identify specific policy changes that will be required within each program. An integrated strategy will be necessary for advancing data

interoperability to support data element and measure alignment for a dQM portfolio across all care settings, including the timeline and associated costs. CMS acknowledges that providers in different care settings vary in their readiness to collect data, standardize it in FHIR, and make it available for exchange through FHIR APIs. To some extent, these differences reflect variation in policies and requirements across the healthcare industry and may be more challenging for providers serving rural areas or underserved populations and small practices. CMS will further review variation in readiness to implement dQMs and identify next steps to support all providers in digital measurement.

Since widespread capability to exchange FHIR-formatted data via APIs is a critical part of the foundation for implementing a common dQM portfolio, the "measure of interoperability" discussed in the Improve Data Quality domain could be used to gauge the success of this transformation. The measure would support providers' transitions from current measure sets to future digital measure sets and incentivize providers to fully comply with ONC requirements. Providers can in turn use the information that this measure would provide to improve their systems. The implementation of this measure could be staged first by CMS's Center for Clinical Standards and Quality (CCSQ), followed by implementation by other CMS centers (such as the Innovation Center) and then federal agencies, states, and private payers.

CMS currently seeks alignment of quality measures through the use of the Meaningful Measures 2.0 framework and has identified several key areas for measurement such as PROs, health equity, patient safety, and digital health capabilities. There are collaboration opportunities across programs within CMS, across federal and state agencies, and with the public and the private sector. Engaging groups such as patients and caregivers; professional and medical specialty societies (beginning with those providers covered by CMS's regulated programs); consensus-setting bodies such as Core Quality Measures Collaborative (CQMC) (a partnership of CMS, NQF, and America's Health Insurance Plans [AHIP]); NQF; quality measure, certification, and accreditation developers such as NCQA; The Joint Commission; private payers; and others, will be important for broad support and consensus in the identification and endorsement of common measure priorities that can be used for development of a dQM portfolio. The CQMC includes key payers (such as Aetna, Blue Cross Blue Shield Association, Cigna, and Humana) who will help define measurement priorities and can help accelerate widespread adoption and implementation of the various actions identified in this strategy.

Accelerate the alignment of data standards and tools across federal agencies, states, and the private sector

Development of FHIR data standards and implementation guides are foundational for this strategy. CMS will collaborate with federal and state agencies and with the private sector to advance and align data and tools that could support the dQM portfolio. Several opportunities already exist. For example:

- *FHIR solutions*: CMS will continue to work with ONC on the use of FHIR APIs for measurement, USCDI and standards alignment, and certification requirements; the U.S. Food and Drug Administration (FDA) on the use of FHIR for real-world-evidence generation; the CDC on the utility of FHIR-based APIs for surveillance and public health reporting such as for COVID-19 and the MedMorph project; and the National Institutes of Health (NIH) and AHRQ on the use of tools for rapid-cycle research, learning, and surveillance. Beyond government agencies, payers, data aggregators, providers, and others are working through HL7 and other forums to expand the use of FHIR resources. For example, the HL7 Gravity Project, led by University of San Francisco's

Social Interventions Research & Evaluation Network, is fostering nationwide consensus through structured processes across multiple stakeholders to identify and harmonize data elements and coding to represent social risk factors beginning with food insecurity, housing instability and homelessness, and transportation insecurity. Use cases and a FHIR implementation guide that will provide guidance on how these data could be documented in electronic systems are also in development.

Another example is the HL7 DaVinci Project,[26] which is focused on the private sector and uses HL7 FHIR as the standard to "support and integrate value-based care data exchange across communities." Through a series of use cases, test scenarios, test data, and an open business model, partners can demonstrate how clinical and administrative data can be managed and shared across entities. CMS can continue to participate and learn from these projects and others to inform the uptake and utility of emerging standards for digital quality measurement.

Additionally, the CDC's Clinical Practice Guidelines (CPG) on FHIR project intends to facilitate the creation of specifications or guidelines concurrent with their development.[27] This work will accelerate the implementation of evidence-based guidelines at the point of care and involves many stakeholders including guidelines developers, clinicians, patients and caregivers, and others. It also is designed to deliver the essential feedback loop of providing real-world data to inform the development and updates to CPGs. Several guidelines have been expressed as computable content including for antenatal care, congestive heart failure, COVID-19, and several immunizations and screenings.

- *Data sharing*: CMS will utilize the industry led HL7 Accelerators and processes to accelerate the development and testing of tools and demonstrate how they can be used for quality measurement. As described in ONC's Federal Health IT Strategic Plan for 2020 — 2025,[28] created by more than 25 federal departments and agencies, supporting exchange of health information will not only drive interoperability but will also support the work of federal agencies.

The COVID-19 pandemic provides opportunities to understand how innovations in digital quality measurement can be achieved. Specifically, it highlighted the importance of aligning tools and data to better care and has accelerated or resulted in efforts to use the FHIR standard, to build national data partnerships with governance in place, and to use PRO data, as described in the case studies on the next page (Figure 16).[29-33]

Figure 16. Case studies on how COVID-19 shifted innovation important for digital quality measurement.

How COVID-19 Shifted Innovation Important for Digital Quality Measurement: Learning Opportunities for Alignment

The COVID-19 pandemic exposed shortcomings of the US healthcare system described in this strategy: lack of data availability, exchange, and interoperability. US health care is composed of siloed, disparate systems, which made for untimely and burdensome manual reporting of COVID-19 cases. The imperative for government agencies and the private sector to adopt base standards, to harness digital technologies, and to work in partnership has never been greater.

The urgency of COVID-19 accelerated federal agencies', providers', and EHR vendors' efforts to understand how best to utilize the existing infrastructure and standard-based interoperability tools to share data, make decisions, and improve care. Public and private programs offered creative approaches to data sharing, using patient-generated data, and collaboration that has supported clinical care and policy decisions in the pandemic. The approaches taken are consistent with this strategy's proposed approach to digital quality measurement aligned across agencies and private payers. Here are three COVID-era born initiatives supporting this vision.

1 Focus on FHIR® to enhance technology solutions enabled timely and efficient data sharing.

All states and territories require COVID-19 case reporting to local public health authorities, but each state has its own requirements. Automating the traditional, manual reporting process was complicated by disparate surveillance. At the beginning of the COVID-19 pandemic, few EHRs had electronic case reporting (eCR) capabilities. In order to minimize burden, the CDC created a FHIR-based, background services app, eCR Now, that could be integrated in existing provider EHRs to automatically identify health events in EHRs, send event information to local public health authorities, and transmit the data to the CDC.

The eCR Now tool extended eCR use to more providers; it allowed non-eCR enabled EHRs to implement the tool in as few as 3 days for automated reporting to connected public health agencies. Public health agencies have used the eCR data to manage the COVID-19 outbreak and response. The eCR Now tool checks trigger codes in events recorded in a provider EHR (based on trigger FHIR queries), determines and confirms the case as a reportable condition, and communicates it to a shared-services platform such as a HIEO or eHealth Exchange, which transmits it to the local jurisdiction. There is also a reportability response back to the patient chart in the provider EHR where the case share originated. Notably, the eCR Now tool can be configured to do broad case reporting beyond COVID-19.

The scaling and uptake of eCR Now illuminated the potential of providers to transmit data to meet reporting requirements in a less cumbersome, real-time manner and for federal and state health agencies to improve surveillance. These data could also be used for future digital quality measurement.

2 Focus on innovative data partnerships led to the development of a platform to collect and share nationwide data for insights on the COVID-19 pandemic.

The National COVID Cohort Collaborative (N3C), is a collaboration between the Clinical and Translational Science Awards (CTSA) Program hubs (60 institutions) and the National Center Data to Health (CD2H) and includes over 600 individuals and 100 organizations, including data networks and clinical partners across the US. The N3C rapidly organized into four community workstreams (data partnership and governance, phenotype and data acquisition, data ingestion and harmonization, and collaborative analytics) to build a solution to advance COVID-19 research. In June 2020, the N3C launched its centralized analytics platform – a data enclave – to systematically collect clinical, laboratory, and diagnostic patient-level EHR data from hospitals across the nation in the cloud environment; standardize the data into a common Observational Medical Outcomes Partnership analytic model; and securely share the data at scale to the N3C community for reproducible COVID-19 research. The platform embodies open science and promotes rapid dissemination of EHR data to its approved users committed to the N3C's Community Guiding Principles of partnership inclusivity, transparency, reciprocity, accountability, and security. The platform supports researchers and providers to identify the impact of COVID-19 including on patient outcomes and SDOH using novel statistical and machine learning methods on a large dataset. CMS's transformation of the quality measurement enterprise to digital will require similar collaboration based on common goals and guiding principles, and implementation design based on function.

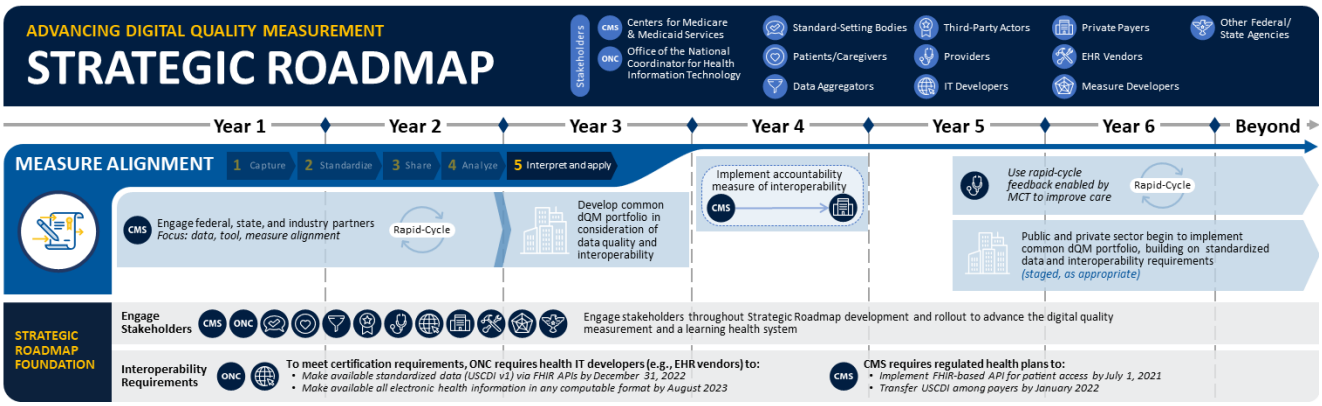
3 Focus on use of PRO data resulted in timely, effective, and efficient patient triage and monitoring, and optimized clinical workflow.

Desert Oasis Healthcare (DOHC) employed a FHIR-based approach to deliver questionnaires to screen, identify, and triage potential COVID-19 patients or those who may have been exposed to the virus, and monitor confirmed COVID-19 patients. The FHIR-based application was integrated within DOHC's EHR and updated based on CDC guidance. DOHC's system distributed automatic queries to patients with upcoming appointments and high-risk groups to detect risks and populate their profiles in FHIR. DOHC providers were able to quickly evaluate at-risk patients and design and communicate care plans based on the information received directly from patients. The PRO data enabled automated follow-ups for DOHC's ongoing monitoring of patients in self-isolation. CMS's dQMs could use data from sources beyond the traditional claims and EHR data such as PRO data, to be patient-centric. Using FHIR-based applications is a promising means to collect these data.

These case studies showcase that building upon the current infrastructure and implementing the pending interoperability requirements will not only improve the healthcare industry in the short, medium, and long terms but also will serve the quality measurement enterprise in the process. They inspire the roles a multitude of stakeholders could play in the transition to digital quality measurement.

Interoperability is a key priority in the industry and a necessary component for CMS's transition to digital quality measurement, among other use cases. CMS will capitalize on the structure of our regulated programs, collaboration with federal and state agencies, and relationships within the industry to facilitate multi-sector, multi-stakeholder engagement to identify mutual priorities; leverage alignment in data, tools, and measurement; and implement and refine the dQM Strategic Roadmap. CMS will work closely with a broad range of stakeholders including patients, consensus- and standard-setting bodies, private payers, providers, data aggregators, professional and medical societies, measure developers, health IT developers and vendors, federal and state agencies, and others. Figure 17 provides an overview of the key milestones of this domain.

Figure 17. Overview of domain 4. *This figure shows the milestones for measure alignment. See the Conclusion for how these milestones and the other domain milestones integrate to support reaching CMS's goal of digital quality measurement.*



Stakeholder Engagement

Our Approach

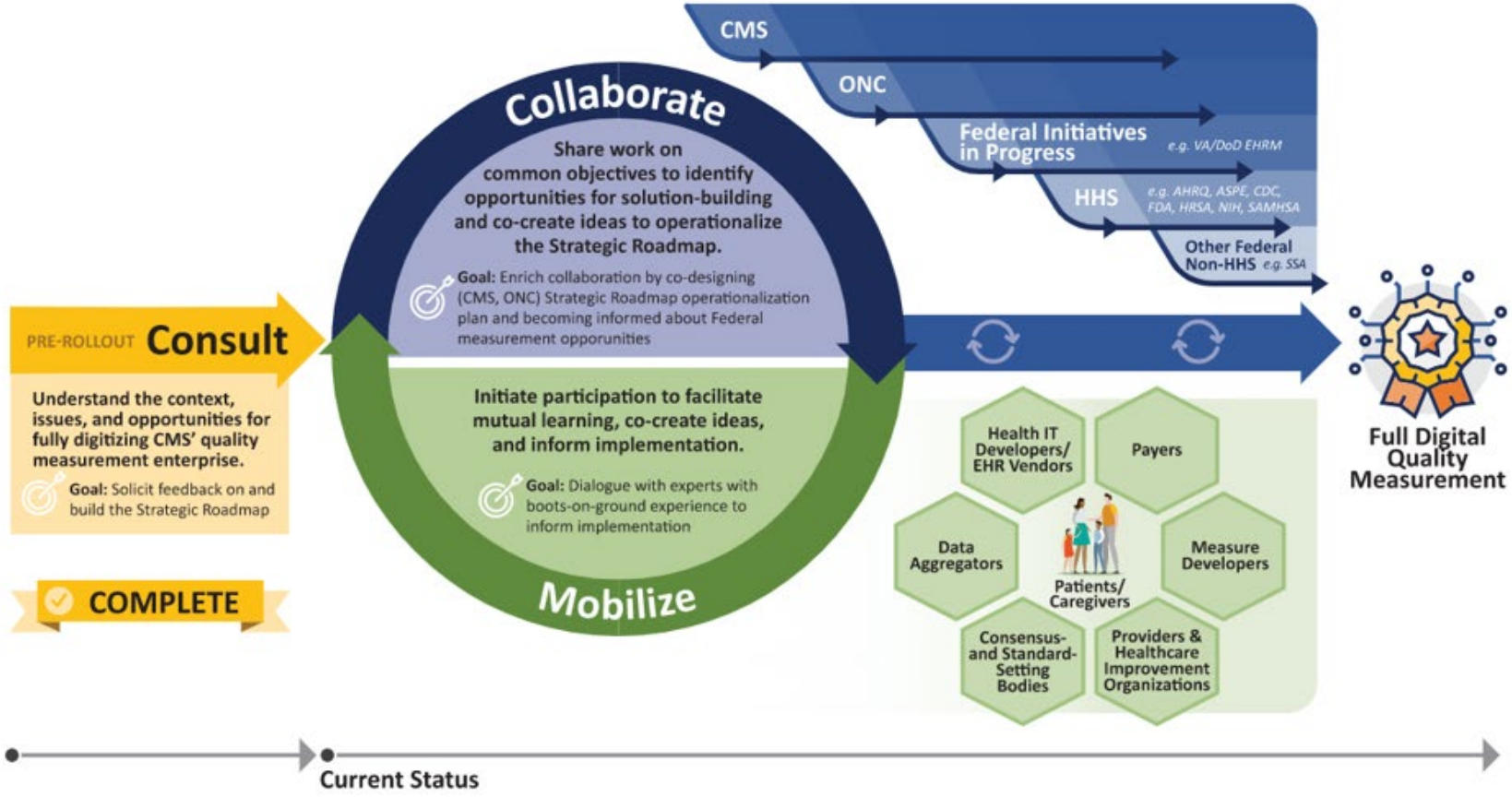
CMS cannot achieve digital quality measurement across all quality reporting programs independently and believes that active engagement with a broad set of stakeholders is critical to the success of forming, operationalizing, and maintaining the dQM Strategy Roadmap. To inform next steps on this work, we focus on the following approach:

1. **Engage with external stakeholders on the dQM Strategic Roadmap and planned modernization activities**

CMS will seek input through existing and emerging processes to facilitate shared learnings, inform implementation strategies, and identify opportunities for co-creating and aligning ideas and solutions. CMS will partner with and directly engage stakeholders by (Figure 18):

- ***Collaborating*** within CMS and with other federal and state agencies. These include, but are not limited to CMS regulated programs, the Innovation Center, and Office of Burden Reduction and Health Informatics as well as other federal and state agencies (for example, ONC, VA/Department of Defense [DoD], AHRQ, Assistant Secretary for Planning and Evaluation [ASPE], CDC, FDA, HRSA, SAMHSA, and the United States Social Security Administration [SSA]). Potential mechanisms for collaborating include CMS quality initiatives, eCQM Governance Group, communities of practice, Interoperability and Standards Collaborative, Measure Collaboration Workspace, listening sessions, and/or contract opportunities (for example, Measure and Instrument Development and Support contracting); HHS's Federal Health IT Coordinating Council and Data Council, ONC's Health IT Advisory Committee (HITAC) and FHIR at Scale Taskforce (FAST), the CDC's Public Health Interoperability Task Force, and the FDA's collaborative communities.
- ***Mobilizing*** industry stakeholders and experts with boots-on-the-ground experience, including patients and caregivers, consensus- and standard-setting bodies, providers, health IT vendors, measure developers, payers, and data aggregators. Potential mechanisms include existing public-private partnerships for reviewing measurement priorities (such as the CQMC and Measure Applications Partnership [MAP]; gaining input on building resources and data infrastructures to support rapid-cycle feedback strategies for providers (such as The Sequoia Project and HL7 Accelerators); and participating in existing meetings and/or conferences within the public and private sectors.

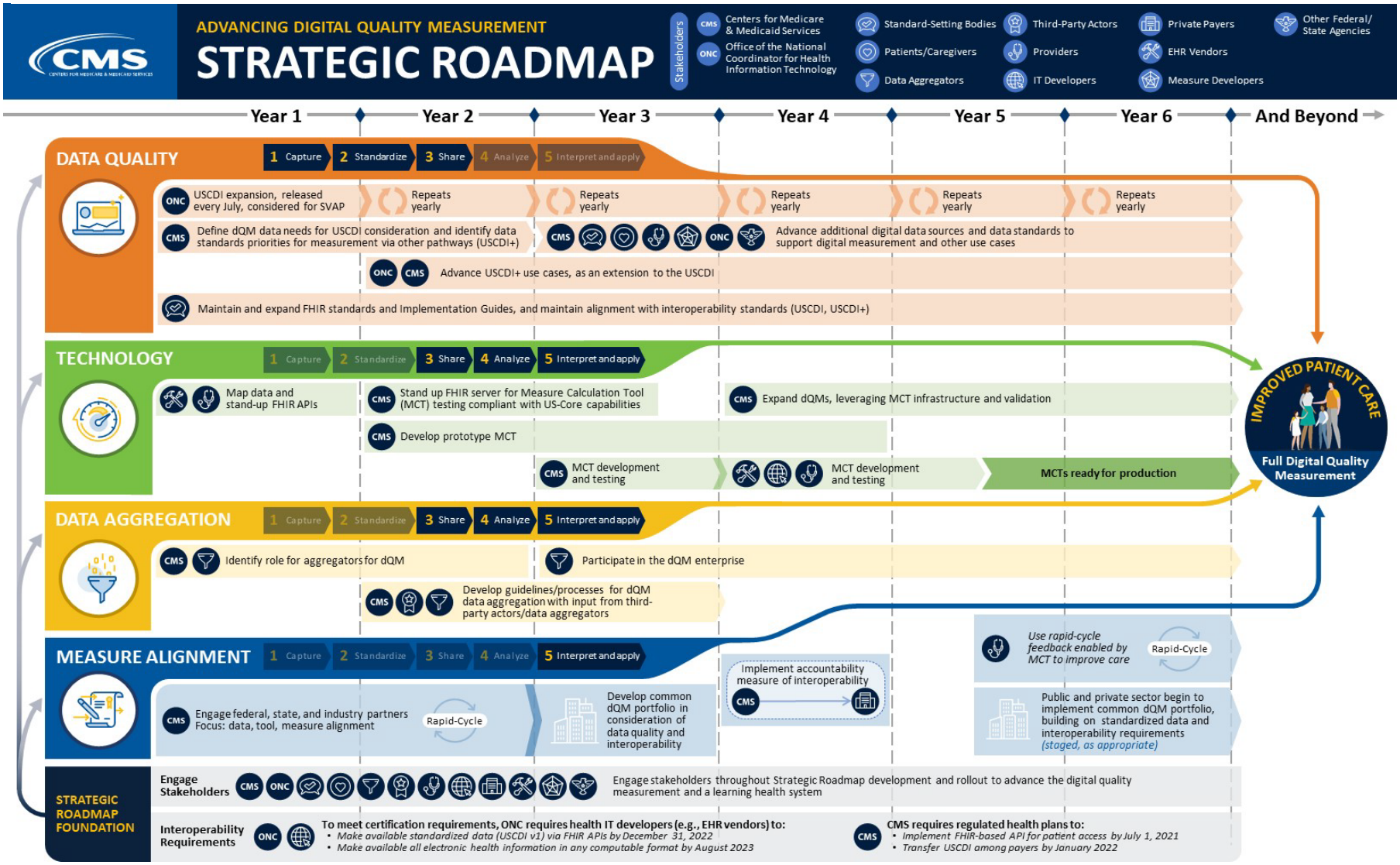
Figure 18. dQM Strategic Roadmap rollout. *This figure shows the spectrum of CMS engagement to develop, implement, and maintain this dQM Strategic Roadmap to advance digital quality measurement. CMS has completed the pre-rollout phase of consulting within the agency to understand the context, issues, and opportunities for fully digitizing its quality measurement enterprise. The rollout will consist of two actions – 1) intra- and inter-agency collaboration and 2) industry mobilization.*



Conclusion

This dQM Strategic Roadmap outlines four key domains to transform CMS's quality measurement enterprise to one that is entirely digital (Figure 19). The accompanying actions suggest a shift both in the way we access data for quality measurement and how we could structure self-contained MCTs to lower measurement burden and foster innovation. This dQM Strategic Roadmap aims to enable data aggregation for measurement and align quality measures broadly across the healthcare ecosystem. Ultimately, we aspire to use more complete, accurate, and comprehensive data, while capitalizing on technology advances to broaden data access and improve the quality measurement enterprise, coordination of care, and ultimately patient care and satisfaction. We recognize that this Strategic Roadmap does not address all related and critical pieces of the quality measurement enterprise, including details related to measure development (testing approaches, measure attribution) and aspects of patient matching, privacy, and security, which will continue to be important as we transition to dQMs. This work will require collaboration with our internal, federal, and state partners, and the private sector to further specify and implement critical actions that will transform CMS's quality measurement enterprise to be digital and overall reflect a healthcare ecosystem with nationwide interoperability.

Figure 19. Critical actions for advancing digital quality measurement. *This figure shows key milestones across the four domains to advance digital quality measurement. Achieving these milestones will require stakeholders to work collaboratively across the public and private sectors to contribute to developing a fully digital quality measurement enterprise that will reflect a healthcare ecosystem with nationwide interoperability.*



Appendices

Appendix A. Glossary

Application programming interface (API): A computing interface that can define interactions between multiple software intermediaries. An API can be customized to a specific component or industry-standard for the purpose of ensuring interoperability.

Certified EHR Technology (CEHRT): A designation of EHR technology offering the necessary technological capabilities, functionalities, and security to meet predetermined requirements and give assurance to purchasers and other users. Certification helps health professionals and patients to have confidence that health IT products and systems can be used in a secure way, maintaining confidential data, and working in conjunction with other information systems. Requirements for CEHRT, in order to qualify for use in the Medicare and Medicaid Promoting Interoperability Programs, are set by CMS and ONC.

Digital data: Data that represent information using specific machine language systems that can be interpreted by various technologies (example: binary).

Digital quality measure (**dQM)**: Quality measures, organized as self-contained measure specifications and code packages, that use one or more sources of health information that is captured and can be transmitted electronically via interoperable systems. dQMs improve the patient experience including quality of care, improve population health, and reduce costs. Data sources for dQMs include administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, laboratory systems, prescription drug monitoring programs (PDMPs), instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated data such as a home blood pressure monitor, or patient-reported health data), health information exchanges (HIEs) or registries, and other sources.

Electronic clinical quality measure (eCQM): A clinical quality measure expressed and formatted to use data from an electronic health record (EHR) to measure healthcare quality, ideally data captured in structured form during the process of patient care. For the eCQM to be reported from an EHR, the Health Quality Measure Format is used to format the eCQM content using the QDM to define the data elements and Clinical Quality Language (CQL) to express the logic needed to evaluate a provider or organization's performance.

Fast Healthcare Interoperability Resources® (FHIR®): An interoperability standard for the electronic exchange of healthcare information. This standard was developed by Health Level Seven International (HL7®) as a draft for trial use to enable health IT developers to promote faster data exchange and retrieval.

Learning health system: As defined by ONC in its Interoperability Roadmap, "an ecosystem where all stakeholders can securely, effectively and efficiently contribute, share and analyze data. A learning

health system is characterized by continuous learning cycles, which encourage the creation of new knowledge that can be consumed by a wide variety of electronic health information systems. This knowledge can support effective decision-making and lead to improved health outcomes."[34]

Measure calculation tool (MCT): A tool that maps the quality measure criterion to the corresponding API endpoint and aggregates the data to perform the requested analysis. Such a tool could be housed within individual provider EHRs, developed and maintained by external health IT vendors, and/or run by CMS for the purpose of quality measurement.

Open-core software: a platform with a standard core architecture available for use under an open-source license supporting an ecosystem of offerings of additional proprietary, closed source add-on functionalities, and services that are not required.

Population health: An approach utilizing non-traditional partnerships among various sectors of the community: public health, industry, academia, healthcare, local government entities, etc. to achieve positive health outcomes. It is also the intersecting and overlapping factors that influence health such as environment, education, mobility, policy and governance, socioeconomic status, race, infrastructure, access to technology, and urban planning.

Quality Improvement (QI) Core Implementation Guide: A guide based on FHIR that defines a set of profiles with extensions and bindings needed to create interoperable, quality-focused applications. The profiles in this implementation guide derive from and extend the US Core profiles to provide a common foundation for building, sharing, and evaluating knowledge artifacts across quality improvement efforts in the US Realm.

Service-oriented architecture: As defined by ONC in its Interoperability Roadmap, "Service-oriented architecture is based on distinct pieces of software providing application functionality as services to other applications via a protocol. Depending on the service design approach taken, each service-oriented architecture service is designed to perform one or more activities by implementing one or more service operations. As a result, each service is built as a discrete piece of code. This makes it possible to reuse the code in different ways throughout the application by changing only the way an individual service interoperates with other services that make up the application, versus making code changes to the service itself. Service-oriented architecture design principles are used during software development and integration."[34]

United States Core Data for Interoperability (USCDI): A standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

United States Core Data for Interoperability Plus (USCDI+): A new initiative established by ONC to support the identification and establishment of domain or program-specific datasets that will operate as extensions to the existing USCDI. In particular, USCDI+ is a service that ONC will provide to federal partners who have a need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI in order to meet agency-specific programmatic requirements.

US Core Implementation Guide (US Core IG): A guide based on FHIR Version R4 that defines the minimum conformance requirements for accessing patient data. This guide is based on the USCDI requirements.

Appendix B. Key Players Definitions/Roles

Centers for Medicare & Medicaid Services (CMS): CMS is a federal agency that strives to improve the quality and safety of care provided to Medicare and Medicaid beneficiaries while reducing costs and increasing transparency through various quality initiatives. CMS implements quality initiatives to assure quality health care for Medicare Beneficiaries through accountability and public disclosure. CMS uses quality measures in its various quality initiatives that include quality improvement, pay for reporting, and public reporting.

Consensus or standard-setting bodies: Organizations that develop standards and frameworks built on agreement across the private and public sphere which are adopted across the healthcare ecosystem. These frameworks span myriad roles, from measure development (for example, NQF) to standard-setting for the sharing of electronic health information (for example, FHIR® standard by HL7®).

Data aggregators: Data aggregators (for example, HIEOs and registries) work to ensure that data are compiled, mapped, validated, and aligned as specified by defined standards. Data aggregators combine data from multiple sources to produce larger sets of data, which enable data centralization, minimize data fragmentation, and buoy data interoperability.

EHR vendors: Vendors (for example, Epic) provide the necessary software and support for EHR adoption by providers.

Government agencies: Organizations tasked with "providing a governance structure, contractual arrangements, rules of engagement, best practices, processes and/or assess compliance" within the health care ecosystem.[35] These organizations can be federal or state.

Health IT vendors/developers: Vendors certified to provide necessary health IT software and support to providers. Though these vendors could also develop EHR technology, this document uses Health IT vendors to describe organizations' non-EHR, health IT contributions. Health IT vendors could develop and maintain an EHR-agnostic MCT.

Office of the National Coordinator for Health Information Technology (ONC): ONC is the principal federal entity responsible for coordinating the nationwide efforts to implement and use the most advanced health IT and the electronic exchange of health information. ONC governs a process to certify EHR systems, referred to as the CEHRT requirements.[36]

Patients and caregivers: People who directly receive health care or who support the health care of others; they are the direct beneficiaries of improved quality and safety of care.

Private payers: Organizations aside from government agencies (for example, insurance companies) who pay for healthcare costs.

Providers: A healthcare professional or organization, including hospitals, clinician practices, and other care settings (for example, rehabilitation center), providing healthcare services to patients.

Quality measure developers: Organizations that define and develop measures that assess quality of health care. These include but are not limited to professional or medical societies, government-contracted developers, federal and state agencies, and not-for-profit organizations.

Third-party certifiers: A non-governmental organization or entity approved by CMS to certify measure calculation tools.

Vendors: Organizations contracted to deliver products that serve a healthcare good or develop a healthcare service. Vendors in this document are further specified as EHR Vendors or Health IT vendors/developers.

Appendix C. Data Sources

Table C1 outlines key data sources for measurement that are a focus of modernization and standardization efforts. This table includes examples of ongoing work to digitize data capture and standardize data where applicable, and highlights potential strategies for digital data that are not yet available.

Table C1. Data Sources for measurement and digital capture/standardization activities

Data Source	Example Measure	Current State of Data Capture/Standardization	Activities to Advance Digital Capture/Standardization
Electronic Health Record (EHR)	eCQMs (for example, CMS 165—Controlling High Blood Pressure eCQM)	DECQ is preparing for future eCQM reporting using the FHIR® standard. Current QDM-CQL specifications are being translated to FHIR-CQL specifications and testing is ongoing.	• Additional work is required to leverage FHIR APIs for measurement, discussed in detail in the Advance Technology domain; and • EHR data prioritized for measurement need to be aligned with interoperability standards, namely the USCDI, USCDI+, and associated FHIR implementation guides.
Claims	30-Day Readmission Measures	Claims data are currently captured and stored electronically. CMS has a robust receiving system for claims.	• To align with the future state goals, claims data submission pathways may be able to be further modernized and streamlined. Data elements included in claims should also be aligned with the interoperability standards; ○ Data terminologies used in claims for diagnoses (International Classification of Diseases, Tenth Revision [ICD-10]) have been included in USCDI; • As part of the CMS Interoperability and Patient Access Rule,[37] claims and encounter data must be made available by payers to patients via FHIR APIs. Learnings and technology from this system can also be leveraged to capture claims data in FHIR standards for measurement, if desired; • HL7® FHIR resources for claims data are being developed;[38] and • CROWNWeb is a CMS data collection system for clinical and administrative claims data that enables longitudinal tracking of renal patients within and across facilities; learnings from this standardized system can be employed.[39]

Data Source	Example Measure	Current State of Data Capture/Standardization	Activities to Advance Digital Capture/Standardization
Survey	Consumer Assessment of Healthcare Providers and Systems (CAHPS®)	CAHPS survey data are currently still captured using some non-digital methods (phone, mail) which are labor intensive and require many manual steps.	• Exploration and expansion of digital modes of survey delivery and data capture, including web and application tools should continue;[40,41] and • Once data are captured digitally, data can be exposed via FHIR or standards-based APIs to streamline data transfer and use.
Assessments	PAC assessments (for example, Inpatient Rehabilitation Facility Patient Assessment Instrument)	Assessments are widely used in the PAC setting, with data capture often occurring outside of the EHR in non-digital and digital formats. CMS continues to support the Data Element Library (DEL) as a centralized resource for CMS assessment instrument data elements and associated health IT standards. The DEL promotes interoperable health information exchange.[42]	• The HL7 Post-Acute Care Interoperability (PACIO)[43] Project is focused on developing standards and FHIR Implementation Guides for assessments used in the PAC programs, to advance data interoperability across care providers; and • Digital capture strategies and standards (FHIR) should continue to be developed and used to expose data in FHIR and data should be considered for inclusion in interoperability standards (USCDI, USCDI+).
	SDOH data	SDOH data are not widely used in quality measurement but identified as a priority area. Data capture is currently variable, and standardization is not always mature.	• Data must be captured routinely and in standard terminology. The Gravity Project[17] and standard-setting bodies should continue development of FHIR standards to advance these data. These data elements should continue to be added to the USCDI and USCDI+; and • CMS will continue to assess how to include SDOH data most appropriately in quality measurement.

Data Source	Example Measure	Current State of Data Capture/Standardization	Activities to Advance Digital Capture/Standardization
Chart-abstracted data (National Healthcare Safety Network [NHSN], medical record)	CDC Hospital Acquired Infection (HAI) measures; PC—01 Elective Delivery	Measures rely on chart-abstracted data via manual processes.	• CDC's NHSN[44] used for HAI measure reporting utilizes web-based tools to automate some aspects of data capture; additional opportunities for automation should be explored; • Burden can be reduced by eliminating the need for chart abstraction on samples and instead enabling the same or similar measurement from digital data on the entire population rather than a sample. • Measures should be carefully evaluated, likely on a case-by-case basis. Some chart-abstracted measures may not be able to be fully digitized, at least in the near term, due to the clinical information and decision-making necessary to confirm outcomes. Chart-abstracted measures should be assessed for use based on impact and priority measurement area and balanced with burden; • Advances in technology, such as NLP, may serve as a path forward for data currently required to be chart abstracted; and • Similarly, AHRQ's improved patient safety surveillance system called the Quality and Safety Review System (QSRS)[45] relies on clinical information recorded in medical records, and the system has been designed to make use of structured data where it is or may become available to automate processes.

Data Source	Example Measure	Current State of Data Capture/Standardization	Activities to Advance Digital Capture/Standardization
Patient-reported data (for example, via instruments like Patient-Reported Outcomes Measurement Information System [PROMIS] and widely used Patient-Reported Outcome Measures [PROMs] such as Hip dysfunction and Osteoarthritis Outcome Score and Knee injury and Osteoarthritis Outcome Score)	PROs following elective primary total hip and/or total knee arthroplasty	PROs are not widely used in measurement, but some measures have been developed and are in early stages of implementation.	• CMS is investigating electronic capture and reporting mechanisms with stakeholder input; • Patient-reported data incorporated into the EHR should align with standards and be included in the USCDI, USCDI+, or supplemental standards; and • FHIR standard development for patient-reported data has made progress, via the Structured Data Capture Implementation Guide and Questionnaire/Questionnaire Response resources[43,46] and should continue as use cases evolve.
Business operations data	Number of beds; location within hospital	Business operations data are routinely captured in EHRs, but not often in a standardized manner. For example, entries are often proprietary to the location since their beds, wings, units, and buildings are all different.	• Data standards (FHIR) should be developed or matured (for example, bed type, staffing, unit); and • As data are prioritized and standards mature, these data can be leveraged for measurement and public health.

Appendix D. Key Actors and Potential Actions

To achieve the ideal future state and move digital quality measurement forward through the key strategy actions outlined in this report, coordinated efforts are necessary across the stakeholder community. Tables D1 – D3 outline key actors and potential actions for the domains of this dQM Strategic Roadmap that should be prioritized to advance digital quality measurement.

Table D1. Key actors and actions for Domain 1: Improve Data Quality

Actor	Potential Action(s)
Strategy: Advance the standardization, transmissibility, and use of digital data	
CMS	• Identify strategies to remain engaged in standards development and maintenance processes, including participating and providing recommendations for standard updates (USCDI, USCDI+, FHIR implementation guides, supplemental standards if needed), key data requirements, and enacting communication channels between CMS divisions and federal agencies to ensure continued alignment; • Identify core data needs to support interoperability and quality measurement across CMS, federal, state, and private payer programs, and use cases; and • Set a strategy for shifting progressively and expanding the arena of dQM data to interoperable standards that allow seamless transmission of data among users.
ONC	• Continue to advance interoperability standards and coordinate work with stakeholders, including CMS and federal agencies, to identify the most critical data elements needed for use cases such as care coordination, quality improvement, research, and measurement for inclusion in standards; and • Set and/or maintain standard schedules for expanding and updating standards including of the USCDI, USCDI+, the SVAP, and CEHRT requirements.
Providers	• Continue to contribute to defining and testing data standards and implementation guides for specific use cases; and • Engage with the USCDI, USCDI+, and supplemental standards setting processes to ensure viability and burden avoidance for collecting the data in the usual course of care and encoding it to proper terminologies.
EHR vendors	• Participate in ONC Certification processes, stand up operable FHIR APIs with USCDI data exposed and continue to expand data content as ONC and CMS requirements are updated.

Actor	Potential Action(s)
Consensus/standard-setting bodies	• Continue to maintain and advance FHIR standards and alignment of USCDI and USCDI+ with implementation guides.
Measure developers	• Continue to align measures with Meaningful Measures focus areas and continue consensus building throughout the development process; and • Clearly define data elements and any additional requirements for measurement (for example, recommend to USCDI next version, USCDI+, or supplemental standards) if specific data are necessary that are not aligned with interoperability data requirements.
Data aggregators	• Offer services to providers to accept data in non-FHIR forms (Consolidated-Clinical Document Architecture, HL-7 2.x, Digital Imaging and Communications in Medicine, etc.) and convert to FHIR; and • Contribute to defining data standards and needs for specific use cases.
Patients/caregivers	• Participate in the USCDI, USCDI+, and standard-setting processes to ensure that patient-reported data, patient satisfaction, and other elements important to individual patient and caregiver decision-making are included; • Advise the process on privacy and security requirements to protect PHI and provide the consumer's perspective; and • Highlight opportunities for burden minimization on patients and caregivers as they increasingly become the primary source for data in quality measurement.
Strategy: Accelerate digital capture and standardization of new data that are critical to advance quality measurement	
CMS	• Continue to identify priority areas for measurement and priority data for capture; and • For priority data not captured digitally or with immature standards, support and engage in digital data strategies and standards development.
ONC	• Coordinate and integrate functional requirements and standards in certified health IT nationwide, including EHRs.
Providers	• Provide input on strategies to digitize data sources and participate in testing.
EHR vendors	• Provide input on strategies to digitize data sources and participate in testing.
Health IT vendors/developers	• Provide input on strategies to digitize data sources and participate in testing.

Actor	Potential Action(s)
Consensus/standard-setting bodies	• Continue to develop standards for the data identified as priority and required for dQMs; and • Be responsive to the USCDI and USCDI+ processes and adopt agile balloting and approval processes to enable new and important measures through the availability of standardized data and implementation guides.
Measure developers	• Develop and test digital specifications based on FHIR-available data.
Patients/caregivers	• Advise on needed data elements and privacy and security concerns.
Strategy: Advance tools and processes to validate data used in measurement	
CMS	• Assess data quality, completeness, and alignment to standards through validation and auditing processes as data are aggregated for measurement; and • Deploy advanced tools and methods for data quality, completeness, and validation, and utilize them as a key component of the measurement reporting process.
Providers	• Ensure that validation processes including data cleaning, completeness, and accuracy are in place; and • Ensure that data exposed via FHIR API are aligned to national standards.
Data aggregators	

Table D2. Key actors and potential actions for Domain 2: Advance Technology

Actor	Potential Action(s)
Strategies: **1) Explore the development of MCTs that are FHIR-based, reliable, and implementable across multiple platforms** **2) Support and certify MCTs developed by others**	
CMS	• Maintain existing MAT and Bonnie tools and/or develop tooling (MADiE) to support FHIR-based measure development activities; • Implement in-house FHIR server; • Explore the development of the MCTs with input from external stakeholders and refine requirements; and • Develop and maintain test cases and standard procedures for testing and versioning to be used for testing and certification.

Actor	Potential Action(s)
ONC	• Maintain certification of interoperability requirements that would enable MCTs to pull EHR data via FHIR APIs; and • Collaborate with CMS on protocols for testing and implementing MCTs given FHIR API and interoperability requirements.
Providers	• Establish and maintain systems supporting FHIR APIs in compliance with CEHRT or connect to make data available to MCTs in a fast and secure manner; and • Actively participate in the testing/validation process for MCTs.
EHR vendors **Health IT vendors/developers**	• Provide input into MCT design, and actively participate in the testing process to ensure that MCTs not only produce accurate measure results but also interface modularly with FHIR APIs or other interoperability standards.
Consensus/standard-setting bodies	• Maintain and advance FHIR standards used for FHIR-based API exchange and other standardized interfaces; and • Enable CMS and other developers to use Connectathons to test MCTs.
Measure developers	• Participate in the development and maintenance of the MCTs; and • Advise and contribute to the development and maintenance of test cases.
Data aggregators	• Develop and implement higher-level operations and use cases for data exchange and establishing trust frameworks for patient-level data; and • Plan and complete policy work required to enable partnership/data sharing with MCTs.
Patients/caregivers	• Review outputs of the MCT process and presentation of results to ensure MCTs produce actionable data for providers and patients while also protecting patient privacy.
Third-party certifiers	• May play a role in certifying MCTs if an ecosystem of them were to arise.

Table D3. Key actors and potential actions for Domain 3: Optimize Data Aggregation

Actor	Potential Action(s)
Strategy: Define and optimize the role of data aggregators to support digital quality measurement ecosystem	
CMS	• Engage with data aggregators that can support dQMs and outline the roles that they could play; and • Provide additional guidance and requirements that may be needed to ensure that data aggregators are equipped to aggregate and report the data required for dQMs.
Providers	• Interact with data aggregators and develop relationships and agreements for support (for example, using TEFCA framework) including support for data validation, quality improvement, and quality measurement reporting.
EHR vendors	• Ensure data flow to data aggregators is comprehensive, high quality, and timely.
Data aggregators	• Provide input to CMS on roles that data aggregators can play in the quality measurement enterprise; • Provide feedback to CMS on any draft data aggregator guidance and requirements; • Continue/begin to perform data validation, identity resolution, and unique services (quality improvement support) for entities in which there is an agreement in place; and • Participate in CMS quality measurement enterprise by aggregating data, performing validation checks, and running MCTs for CMS program measures on behalf of providers, and providing data to CMS as needed.
Patients/caregivers	• Engage in the governance of patient data at local HIEO or other data aggregator; and • Participate in the development of data aggregator strategies at CMS and ONC.

Table D4. Key actors and potential actions for Domain 4: Enable Measure Alignment

Actor	Potential Action(s)
Strategies: **1) Develop a common dQM portfolio aligned across programs, agencies, and payers** **2) Accelerate the alignment of data standards and tools across federal agencies, states, and the private sector**	
CMS	• Engage stakeholders (such as federal, state, industry partners) to learn and to align on digital quality measurement priorities that build on standardized and interoperable data capabilities, and to inform the development of a common dQM portfolio; and • Consider development and subsequent implementation of a transition measure of interoperability to assess FHIR API functionality and data quality for CMS use for quality measurement.
ONC	• Provide input on measure specifications for a potential measure of interoperability as it interacts with CEHRT and other potential certification processes.
Standards-setting bodies, patients/caregivers, data aggregators, third-party actors, providers, IT developers, private payers, EHR vendors, measure developers, other federal/state agencies	• Provide input on development of common dQM portfolio led by CMS; • Begin to implement common dQM portfolio building on standardized and interoperability requirements; and • (Providers) Use rapid-cycle feedback from dQMs to improve care.

Appendix E. Measure Calculation Tools Implemented by Various Entities

As described in the Advance Technology domain, the MCTs could be implemented by multiple entities and we show the implementation of the MCTs by external entities such as HIEOs, quality measurement vendors, or data aggregators/calculators (Figure 9).

The following figures outline the functions of the MCTs if they were implemented by CMS (Figure E1) or by a third party such as a data aggregator (Figure E2).

Figure E1. CMS develops and implements the MCTs referred to as QualiFHIR. *In this scenario, the provider EHR (in yellow) would transform patient data elements specified in the USCDI or USCDI+ to a standardized FHIR data model. These data elements would be stored in the provider's FHIR® server within API endpoints, ready to be delivered when requested to an MCT, which is maintained by an outside party. When CMS (in blue) sends a measure report request to an MCT (in green) housed and maintained within CMS, the MCT discerns the data needed for the measure and queries the FHIR API within a provider's EHR at its endpoints for the necessary data elements. After receiving the data, the MCT further formats the data for analysis and calculates a measure score as specified by the measure definition. This measure score is provided within CMS for quality measurement and improvement only.*

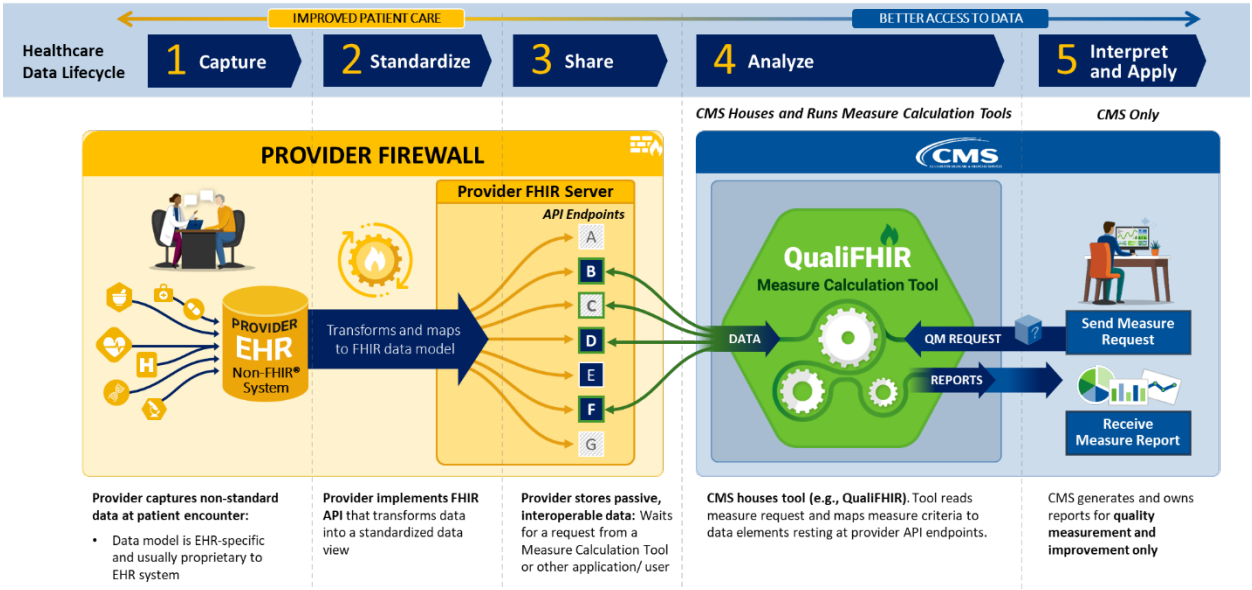
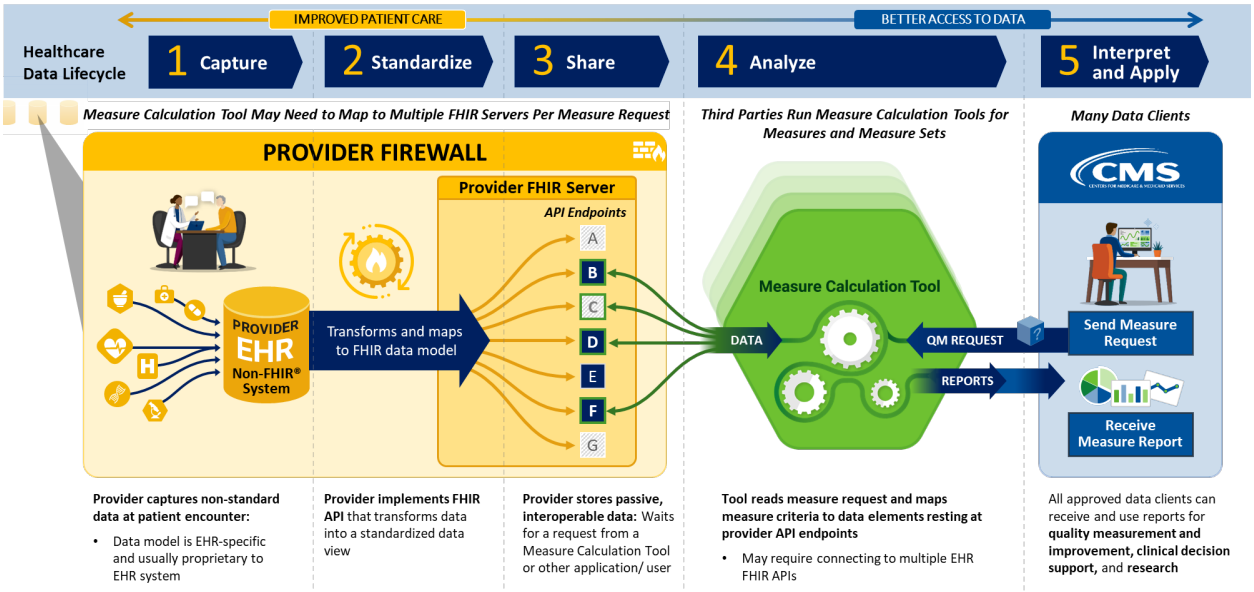


Figure E2. Example of separate, EHR-agnostic measure calculation tool(s) implemented by a third party such as an HIEO, a quality measurement contractor, or a data aggregator/calculator*. In this scenario, the provider EHR (in yellow) would transform patient data elements specified in the USCDI or USCDI+ to a standardized FHIR® data model. These data elements would be stored in the provider's FHIR server within API endpoints, ready to be delivered when requested to an MCT, which is maintained by an outside party. When CMS (in blue) sends a measure report request to an MCT (in green) that sits within a provider's firewall, the MCT discerns the data needed for the measure and queries the FHIR API within a provider's EHR at its endpoints for the necessary data elements. After receiving the data, the MCT further formats the data for analysis and calculates a measure score as specified by the measure definition. This measure score is delivered to CMS for quality measurement and improvement and is available to approved data clients.*



Appendix F. List of Acronyms

ACRONYM	DEFINITION OF ACRONYM
AHIP	America's Health Insurance Plans
AHRQ	Agency for Healthcare Research and Quality
AI	Artificial Intelligence
API	Application Programming Interface
ASPE	Assistant Secretary for Planning and Evaluation
CAHPS®	Consumer Assessment of Healthcare Providers and Systems
CDC	The Centers for Disease Control and Prevention
CEHRT	Certified Electronic Health Record Technology
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus Disease 2019
CPG	Clinical Practice Guidelines
CQL	Clinical Quality Language
CQMC	Core Quality Measures Collaborative
CROWNWeb	Consolidated Renal Operations In a Web-Enabled Network
DECQ	Division of Electronic and Clinical Quality
DEL	Data Element Library
DoD	United States Department of Defense
dQM	Digital Quality Measure
eCQM	Electronic Clinical Quality Measure
EHR	Electronic Health Record
FAST	FHIR at Scale Taskforce
FDA	United States Food and Drug Administration
FHIR®	Fast Healthcare Interoperability Resources®
HAI	Healthcare-Associated Infections
HHS	United States Department of Health and Human Services
HIEO	Health Information Exchange Organization

ACRONYM	DEFINITION OF ACRONYM
HITAC	Health Information Technology Advisory Committee
HL7®	Health Level Seven International®
HRSA	Health Resources and Services Administration
ICD-10	International Classification of Diseases, Tenth Revision
IT	Information Technology
LOINC®	Logical Observation Identifiers Names and Codes®
MADiE	Measure Authoring Development Integrated Environment
MAP	Measure Applications Partnership
MAT	Measure Authoring Tool
MCT	Measure Calculation Tool
MedMorph	Making EHR Data More Available for Research and Public Health
MIPS	Merit-Based Incentive Payment System
NCQA	National Committee for Quality Assurance
NHSN	National Healthcare Safety Network
NIH	National Institutes of Health
NLP	Natural Language Processing
NQF	National Quality Forum
ONC	Office of National Coordinator for Health Information Technology
PAC	Post-Acute Care
PACIO	Post-Acute Care Interoperability
PDMP	Prescription Drug Monitoring Programs
PGHD	Patient-Generated Health Data
PHI	Protected Health Information
PRO	Patient-Reported Outcome
PROM	Patient-Reported Outcome Measure
PROMIS	Patient-Reported Outcomes Measurement System
PRO-PM	Patient-Reported Outcome Performance Measure

ACRONYM	DEFINITION OF ACRONYM
QDM	Quality Data Model
QI	Quality Improvement
QSRS	Quality and Safety Review System
SAMHSA	Substance Abuse and Mental Health Services Administration
SDOH	Social Determinants of Health
SVAP	Standards Version Advancement Process
TEFCA	Trusted Exchange Framework and Common Agreement
US Core IG	US Core Implementation Guide
USCDI	United States Core Data for Interoperability
USCDI+	United States Core Data for Interoperability Plus
VA	United States Department of Veterans Affairs

References

1. Social Security Act, 42 U.S.C. 1395aaa §1890A (1935).
2. The Office of National Coordinator for Health Information Technology (ONC). Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs. February 21, 2020. Accessed March 7, 2022. https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.
3. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642 (May 1, 2020) (to be codified at 45 C.F.R. Parts 170 and 171).
4. Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency, 85 Fed. Reg. 70064 (November 4, 2020).
5. Medicare and Medicaid Programs, Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. 85 Fed. Reg. 25510 (May 1, 2020) (to be codified at 42 C.F.R. Parts 406, 407, 422, 423, 431, 438, 457, 482, and 485).
6. The Office of the National Coordinator for Health Information Technology (ONC). USCDI+. Published 2021. Accessed March 7, 2022. https://www.healthit.gov/topic/interoperability/uscdi-plus.
7. Centers for Medicare & Medicaid Services (CMS). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Accessed March 7, 2022. https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.
8. The Office of National Coordinator for Health Information Technology (ONC). Trusted Exchange Framework and Common Agreement (TEFCA) v2. 2019; 88. April 19, 2019. Accessed March 7, 2022. https://www.healthit.gov/sites/default/files/page/2019-04/FINALTEFCAQTF41719508version.pdf.
9. Department of Veteran's Affairs (VA). Electronic Health Record Modernization 2020;. Accessed March 7, 2022. https://www.ehrm.va.gov/.
10. The Core Quality Measures Collaborative (CQMC). AHIP, CMS, and NQF Partner to Promote Measure Alignment and Burden Reduction. Accessed March 7, 2022. https://www.qualityforum.org/cqmc/.
11. The National Quality Forum (NQF). Measure Applications Partnership (MAP). Accessed March 7, 2022. http://www.qualityforum.org/map/.
12. The Office of National Coordinator for Health Information Technology (ONC). Patient Identity and Patient Record Matching. Accessed March 7, 2022. https://www.healthit.gov/topic/patient-identity-and-patient-record-matching.
13. Argentieri R, Myers E, Posnack S, Tripath M. Thinking Outside the Box: The USCDI+ Initiative. Health IT Buzz. Published 2021. Accessed March 7, 2022. https://www.healthit.gov/buzz-blog/health-it/thinking-outside-the-box-the-uscdi-initiative.

14. The Office of National Coordinator for Health Information Technology (ONC). Draft USCDI Version 2. January 13, 2021. Accessed March 7, 2022. https://www.healthit.gov/sites/default/files/facas/2021-01-13_Draft%20USCDI_Version_2_Presentation.pdf.
15. Improving Medicare Post-Acute Care Transformation Act of 2014, H.R. 4994. §§113–185 (2014).
16. Centers for Medicare & Medicaid Services (CMS). ESRD Quality Incentive Program. Accessed March 7, 2022. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP.
17. Health Level 7 International (HL7). Gravity Project. Published 2018. Updated November 01, 2019. Accessed March 7, 2022. http://www.hl7.org/gravity/.
18. The National Committee for Quality Assurance (NCQA). HEDIS Compliance Audit Certification. Published 1995. Accessed March 7, 2022. https://www.ncqa.org/programs/data-and-information-technology/hit-and-data-certification/hedis-compliance-audit-certification/.
19. Centers for Medicare & Medicaid Services (CMS). Medicare Fee-for-Service Compliance Programs. Published 2020. Accessed March 7, 2022. https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Overview.
20. The National Quality Forum (NQF). A Measurement Framework to Assess Nationwide Progress Related to Interoperable Health Information Exchange to Support the National Quality Strategy. Published 2017. Accessed March 7, 2022. http://www.qualityforum.org/Publications/2017/09/Interoperability_2016-2017_Final_Report.aspx.
21. The National Quality Forum (NQF). Effective Communication and Care Coordination Published 2020. Accessed March 7, 2022. https://www.qualityforum.org/Topics/Effective_Communication_and_Care_Coordination.aspx.
22. The Strategic Health Information Exchange Collaborative (SHIEC). The Strategic Health Information Exchange Collaborative (SHIEC). Published 2020. Accessed March 7, 2022. https://strategichie.com/about/.
23. The Office of National Coordinator for Health Information Technology (ONC). Patient Identity and Patient Record Matching. Department of Health and Human Services (HHS). Published 2020. Accessed March 7, 2022. https://www.healthit.gov/topic/patient-identity-and-patient-record-matching.
24. Patient ID Now. Patient ID Now. Accessed March 7, 2022. https://patientidnow.org/.
25. The National Committee for Quality Assurance (NCQA). Data Aggregator Validation Early Adopter Phase Launched. Published 2020. Accessed March 7, 2022. https://www.ncqa.org/programs/data-and-information-technology/hit-and-data-certification/hedis-compliance-audit-certification/data-aggregator-validation/.
26. Health Level 7 International (HL7). Da Vinci Project. Published 2019. Updated November 01, 2019. Accessed March 7, 2022. http://www.hl7.org/about/davinci/index.cfm.
27. Health Level 7 International (HL7). FHIR Clinical Guidelines. Accessed March 7, 2022. http://build.fhir.org/ig/HL7/cqf-recommendations/.
28. The Office of the National Coordinator for Health Information Technology (ONC), United States Department of Health and Human Services (HHS). 2020-2025 Federal Health IT Strategic Plan. Published 2020. Accessed March 7, 2022. https://www.healthit.gov/sites/default/files/page/2020-10/Federal%20Health%20IT%20Strategic%20Plan_2020_2025.pdf.

29. Centers for Disease Control and Prevention (CDC). eCR Now: COVID-19 Electronic Case Reporting. U.S. Department of Health & Human Services. Published 2020. Accessed March 7, 2022. https://www.cdc.gov/coronavirus/2019-ncov/php/electronic-case-reporting.html.
30. The Office of the National Coordinator for Health Information Technology (ONC). Interoperability Proving Ground. Published 2020. Accessed March 7, 2022. https://www.healthit.gov/techlab/ipg/.
31. The CTSA Program National Center for Data to Health (CD2H), National Center for Advancing Translational Sciences (NCATS). N3C Data Enclave. Published 2020. Accessed March 7, 2022. https://covid.cd2h.org/.
32. Haendel MA, Chute CG, Bennett TD, et al. The National COVID Cohort Collaborative (N3C): Rationale, design, infrastructure, and deployment. *Journal of the American Medical Informatics Association.* 2020. doi: 10.1093/jamia/ocaa196.
33. Williams C, Holdings VP. Rimidi Demonstrates Effectiveness of FHIR-based Patient Reported Outcomes Tool For COVID-19 Screening, Triage and Monitoring. *PRWeb.* 2020. https://www.prweb.com/pdfdownload/17255608.pdf.
34. The Office of National Coordinator for Health Information Technology (ONC). Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap FINAL Version 1.0. Published 2015. Accessed March 7, 2022. https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf.
35. The Office of National Coordinator for Health Information Technology (ONC). Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap FINAL Version 1.0. Published 2015. Accessed March 7, 2022. https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf.
36. The Office of National Coordinator for Health Information Technology (ONC). About ONC. Accessed March 7, 2022. https://www.healthit.gov/topic/about-onc.
37. Medicare and Medicaid Programs, Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers. Fed. Reg. 25510 (May 1, 2020).
38. Health Level 7 International (HL7). Financial Management. Accessed March 7, 2022. http://www.hl7.org/Special/committees/fm/index.cfm.
39. Centers for Medicare & Medicaid Services (CMS), Oniel Delva. In The Know: How Dialysis Facilities Report Patient Data. Published 2014. Accessed March 7, 2022. https://mycrownweb.org/in-the-know-how-dialysis-facilities-report-patient-data/.
40. Agency for Healthcare Research and Quality (AHRQ). Advances in Survey Methodology: Maximizing Response Rates and the Representativeness of CAHPS® Survey Data Meeting Summary Advances in Survey Methodology: Maximizing Response Rates and the Representativeness of CAHPS® Survey Data Web site. Published 2019. Accessed March 7, 2022. https://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/survey-methods-research/summary-research-meeting.pdf.
41. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Medicare Shared Savings Program Requirements; Quality Payment Program; Medicaid Promoting Interoperability Program; Quality Payment Program-Extreme and Uncontrollable Circumstance Policy for the 2019 MIPS Payment Year; Provisions From the Medicare Shared Savings Program-Accountable Care Organizations-Pathways to Success; and Expanding the Use of Telehealth Services for the Treatment of Opioid Use Disorder

Under the Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act; Correction, 85 Fed. Reg. 9460 (March 15, 2019).
42. Centers for Medicare & Medicaid Services (CMS). Data Element Library. Accessed March 7, 2022. https://del.cms.gov/DELWeb/pubHome.
43. Health Level 7 International (HL7). PACIO Cognitive Status Implementation Guide (FHIR IG). Published 2014. Updated November 01, 2019. Accessed March 7, 2022. http://hl7.org/fhir/us/pacio-cs/history.html.
44. Centers for Medicare & Medicaid Services (CMS). National Healthcare Safety Network (NHSN). Published 2020. Updated 2021. Accessed March 7, 2022. https://www.cdc.gov/nhsn/enrolled-facilities/index.html.
45. Agency for Healthcare Research and Quality (AHRQ). AHRQ Quality and Safety Review System (QSRS). Published 2016. Accessed March 7, 2022. https://www.ahrq.gov/patient-safety/resources/qsrs/index.html.
46. Health Level 7 International (HL7). Structured Data Capture FHIR IG. Published 2015. Updated November 01, 2019. Accessed March 7, 2022. http://hl7.org/fhir/uv/sdc/history.html.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