Bipartisan Policy Center and Health Leadership Council

INTEROPERABILITY POLICY BRIEF

February 11, 2019

CONTENTS

WHAT IS INTEROPERABILITY AND WHY IS IT IMPORTANT?

Interoperability is an urgent healthcare and health information technology (health IT) priority. As the industry has become increasingly digitized[*], opportunities for value from interoperability have never been higher.[1] Indeed, this arcane topic has received White House attention and become a high-profile Administration initiative,[2,3,4] taking center stage in the 2018 revamp[5] of the CMS incentive payment programs and the release of the proposed rules by the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) in February 2019.

So, what is interoperability? An often-cited definition by the IEEE is the "ability of a system or a product to work with other systems or products without special effort on the part of the customer. Interoperability is made possible by implementation of standards."[6] ONC adapted this definition to health IT as: "the ability of systems to exchange and use electronic health information from other systems without special effort on the part of the user. ONC's overarching goal for electronic health information exchange is for information to follow a patient where and when it is needed, across organizational, health IT developer and geographic boundaries."[7]

For medical devices, the U.S. Food and Drug Administration (FDA) defines interoperability as "the ability to safely, securely, and effectively exchange and use information among one or more devices, products, technologies, or systems. This exchanged information can be used in a variety of ways including display, store, interpret, analyze, and automatically act on or control another product."[8] Safety is explicit as a pressing concern for device interoperability and for health care generally; accurate and timely data are key determinants of safe care.[9,10]

HIMSS offers its own complementary definition, "the extent to which systems and devices can exchange data and interpret that shared data. For two systems to be interoperable, they must be able to exchange data and subsequently present that data such that it can be understood by a user".[11] HIMSS goes on to provide a more detailed definition, with three progressively demanding and value-laden levels:

> "In healthcare, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged. Data exchange schema and standards should permit data to be shared across clinician, lab, hospital, pharmacy, and patient regardless of the application or application vendor.
>
> Interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of

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[*]Hospitals and providers are using interoperable health IT at very high levels as detailed in the section on the Current State of Interoperability. In 2008, only 16.97% of physicians and 9.4% of hospitals had at least a basic electronic health record (EHR). By 2015, 96% of hospitals used certified EHR technology. By 2017, 79.7% of office-based physicians used certified EHR technology.

healthcare for individuals and communities. There are three levels of health information technology interoperability:

1. "Foundational" interoperability allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data.

2. "Structural" interoperability is an intermediate level that defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of healthcare data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between . . . systems can be interpreted at the data field level.

3. "Semantic" interoperability . . . the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged. Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that the receiving information technology systems can interpret the data.

In general, *semantic interoperability* is what most are aspiring to when they discuss this topic.

In late 2016, the U.S. Congress enshrined a definition in federal law. Section 4003 of the 21st Century Cures Act (Cures)[12], building on the IEEE definition, and reflecting then current policy priorities, defines "interoperability" as health IT that:

- "Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

- Does not constitute information blocking."

In Section 4004, the Cures Act defines *information blocking* as "a practice that:

- Is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information;

- If conducted by a health IT developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; and

- If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information."

The goal of interoperability is *data liquidity, the* right data to the right person at the right time.[13] Concepts reoccur across these definitions, some aspirational and some in conflict:

- Systems or products *working with other systems or products*
- *Within and across organizations*
- *No special effort* by customer/user
- *Standards*
- *Exchange* of data
- *Use* of data (beyond exchange)
- *Information follows* the *patient*
- Data *where and when needed*
- *Availability across boundaries*

- *Effective delivery of healthcare* for *individuals* and *communities*
- *Computable data: structured*, using *standard codes and vocabularies*
- *Safety*
- *Complete access* to *all electronically accessible health information*
- *Authorized use* under *applicable State or Federal law*
- *No interference with access, exchange, or use* of *electronic data*

There are many technologies, models, and standards designed to achieve interoperability for specific use cases[†]. Many public and private sector stakeholders are focusing on standards-based open Application Programming Interfaces (APIs)[14] using the HL7® Fast Healthcare Interoperability Resource (FHIR®) standard[15], to enable these goals to be realized, along with continued growth and refinement to existing health data standards, technologies, and frameworks.[16] Opportunities from APIs are driving renewed optimism (and hype) about near-term interoperability. The emphasis is on patient-centric interoperability[17], with data following the patient, who is the conduit or enabler for access by other parties, including their providers.

The value of interoperability <u>is</u> the value of digitizing healthcare, enabling access to useful and usable information by healthcare participants (e.g., patients and families, clinicians, healthcare organizations, payers, consumers, developers, and researchers) in a manner and timeframe that can lead to:

- Better health outcomes for individuals in the U.S.; and
- Higher quality, safer, more cost-effective care for individuals and populations.

In health IT, as in other fields, interoperability is situational and not one thing. It is defined by specific technologies, current state of the art, use cases, business rationale to support investments, and state and federal laws and regulations. The

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[†] A use case is a list of actions or steps defining interactions between a role (often referred to as an "actor") and a system to achieve a goal. An example is provider to provider exchange of data to support patient treatment. Another is patient access to longitudinal electronic health record data to support informed personal healthcare decision-making. Adapted from https://en.wikipedia.org/wiki/Use_case.

challenge (and opportunity) is the right balance of public and private sector initiatives, business models, and technology to achieve these goals.

SUMMARY OF MAJOR INTEROPERABILITY INITIATIVES

U.S. Federal Government

Office of the National Coordinator for Health IT

ONC has various interoperability policy and implementation initiatives underway.[18]

1. Interoperability Roadmap

   In October 2015, ONC released *Connecting Health and Care for the Nation A Shared Nationwide Interoperability Roadmap*.[19] High levels goals are:

   - 2015-2017: Send, receive, find and use priority data domains to improve health care quality and outcomes.
   - 2018-2020: Expand data sources and users in the interoperable health IT ecosystem to improve health and lower costs.
   - 2021-2024: Learning health system, with the person at the center of a system that can continuously improve care, public health, and science through real-time data access.

   The Roadmap emphasizes the first goal and its milestones, critical actions, and associated commitments. It calls out four *critical pathways* for stakeholders:

   A. Improve technical standards and implementation guidance for priority data domains and associated elements. In the near-term, the Roadmap focuses on using available standards, while pushing for greater implementation consistency and innovation associated with new standards and technology approaches, such as APIs.

   B. Rapidly shift and align federal, state, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability.

   C. Clarify and align federal and state privacy and security rules enabling interoperability.

   D. Coordinate among stakeholders to promote and align consistent policies and business practices that support interoperability and address those that impede interoperability.

   The Roadmap has three sections: Drivers, Policy and Technical Components, and Outcomes (i.e., metrics to assess progress).

   The ONC Roadmap remains a valuable and relevant resource for interoperability planning and policy development.

2. Interoperability Standards Advisory (ISA)

ONC uses the Interoperability Standards Advisory (ISA) to coordinate "identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the healthcare industry to address specific interoperability needs including, but not limited to, interoperability for clinical, public health, and research purposes".[20] The latest version is the 2019 ISA[21], which includes clinical, research, and administrative standards and evaluates standards by maturity and adoption level. The ISA focuses on inter-organizational data sharing. ONC recently had a formal comment period seeking input on potential ISA revisions, some of which are reflected in the 2019 ISA.

The ISA is not a normative (i.e., recommended or required) listing of standards to use for specific purposes but rather, a "coordinated catalog of standards and implementation specifications that can be used by different stakeholders to consistently address a specific interoperability need." Indeed, it sometimes identifies multiple standards for a specific need, often reflecting established/mature vs. emerging status. ONC has implemented a web-based process using an ongoing comment model. It emphasizes that the ISA is non-binding but also that some of its components may be selected for future regulatory inclusion.

> *The ISA is a useful and dynamic compendium. Its value is limited, however, by lack of clarity on what stakeholders should do with its information and the extent to which inclusion in the ISA foreshadows regulatory requirements.*

3. U.S. Core Data for Interoperability (USCDI)

In January 2018, ONC released an implicit companion to the ISA that is more normative, with a roadmap for expansion. This *Draft U.S. Core Data for Interoperability (USCDI) and Proposed Expansion Process* was issued with a 45-day comment period.[22] It proposes a process to expand in annual increments from the Common Clinical Data Set (CCDS)[23] defined in the 2015 edition ONC Health IT certification criteria. The CCDS is used in ONC's certification process and CMS Health IT incentive programs to define the minimum data to be exchanged or available via exchange.

The USCDI sets out ONC's vision of expanding in step-wise and careful fashion from the CCDS to the "all electronically accessible health information" goal included in the 21st Century Cures interoperability definition. It specifies "a common set of data classes [e.g., medications, clinical notes, smoking status, etc.] that are required for interoperable exchange . . . identifying a predictable, transparent, and collaborative process for achieving those goals." The USCDI would be the expected minimum data set to be exchanged under the new Trusted Exchange Framework and Common Agreement (TEFCA) discussed in the next section and likely would, over time, replace the CCDS in such programs as ONC health IT certification, the EHR Incentive Program (i.e., meaningful use), MIPS, and the new CMS Promoting Interoperability Program (see the CMS discussion in this policy brief for more on this proposal)[24]. Comments on the USCDI received by ONC emphasize needed coordination and clarity vis a vis the ISA.

The USCDI is an important mechanism to expand the standardized data available for exchange at a national level. It will benefit from the comments received by ONC, including those by the Health IT Advisory Committee (HITAC)[25].

Trusted Exchange Framework and Common Agreement (TEFCA)

The Administration set out its updated vision for achieving nationwide interoperability in the *Draft Trusted Exchange Framework*[26], which was issued with a 45-day comment period in January 2018. This proposal is part of ONC's response to the 21st Century Cures Act requirement for HHS to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally."[27] This requirement is known as the Trusted Exchange Framework and Common Agreement (TEFCA).

The Draft Trusted Exchange Framework (TEF) has five goals (also in the USCDI proposal) to bring about an interoperable healthcare system:

Goal 1: Build on and extend existing work done by the industry

Goal 2: Provide a single "on-ramp" to interoperability for all

Goal 3: Be scalable to support the entire nation

Goal 4: Build a competitive market allowing all to compete on information services

Goal 5: Achieve long-term sustainability

The draft TEF has two parts. Part A-Principles for the Trusted Exchange Framework has general principles "designed to provide guardrails and promote trust between Health Information Networks based on the current state of existing trusted exchange frameworks". Part B-Minimum Required Terms and Conditions, operationalizes the Part A principles and identifies minimum terms and conditions to be required of all TEFCA participants. The TEF focuses primarily on enabling the technical and policy framework to permit nationwide *queries* (i.e., requests for information, as distinct from unsolicited *pushes* of information) for the data contained in the USCDI, whether in document form (e.g., the HL7 C-CDA data document standard) or as data elements.

ONC proposes to designate, via a Cooperative Agreement, a single private sector Recognized Coordinating Entity (RCE) that will work with ONC to finalize the TEF and develop a single Common Agreement (CA) that Qualified Health Information Networks (Qualified HINs) and their participants can voluntarily adopt. ONC initially stated its intention to designate the RCE by August after a funding announcement this past spring, with the final TEFCA to be published late in 2018 in the *Federal Register*. ONC has since indicated that it will release a revised TEF for public comment[28] and has not yet issued the funding announcement or designated an RCE.

In publishing the draft TEF, ONC affirmed its priority interoperability goals:[29]

- *Patients* must be able to access their health information electronically *without any special effort*;

- *Providers and payer organizations accountable for managing benefits* can receive *population level health information* allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives; and

- The health IT community should have *open and accessible APIs* to encourage *entrepreneurial, user-focused innovation* to make health information more accessible and to improve electronic health record (EHR) *usability*.

Reflecting these goals and concepts, the Draft TEF cites six permitted purposes that TEFCA participants will be expected to support: Public Health, Benefits Determination, Individual Access. Treatment, Healthcare Operations, and Payment, plus three priority use cases:

- *Broadcast Query*: Sending a request for a patient's Electronic Health Information (EHI) to all QHINS to have data returned from all organizations who have it—supports situations where it is unknown who may have EHI about a patient.

- *Directed Query*: Sending a targeted request for a patient's EHI to a specific organization(s)—supports situations where a requester wants specific Electronic Health Information about a patient, for example data from a particular specialist.

- *Population Level Data Query*: Querying and retrieving EHI about multiple patients in one query—supports population health services, such as quality measurement, risk analysis, and analytics.

This draft was reviewed by the new HIT Advisory Committee (HITAC)[30] created by the Cures Act. The HITAC made several recommendations to ONC, reflecting and refining themes in the many, often critical[31], formal comments received by ONC.

> The TEFCA, as finalized based on public comments, will play a major role in public and private sector interoperability efforts over the next few years and will be closely intertwined with enforcement of Information Blocking prohibitions. In early 2019, ONC is expected to issue a Proposed Rule that will address how organizations can sign-on to the TEFCA as well as proposals addressing "reasonable and necessary" exceptions to the Cures Act prohibition of information blocking. It will also propose how various Cures concepts will be integrated into ONC certification. **The public and private sectors should leverage and refine the TEFCA as it is implemented.**

> Although the use cases and permitted purposes in the Draft TEF clearly support provider-provider interoperability using well-established interoperability models (e.g., document query), ONC's goals (and public statements of ONC and CMS leadership) seem primarily focused on patient-centric (i.e., data follows the patient) and payer-centric interoperability models. These would use new technology approaches, such as APIs, to support a smartphone/app environment and use data liquidity to enhance competition in healthcare delivery and technology.[32]

4. Health IT Certification

The ONC Health IT Certification Program is a voluntary program that certifies health IT to standards, implementation specifications and certification criteria adopted by the HHS Secretary.[33] The program is designed to enable availability of certified health IT for a range of federal, state and private programs, most notably, those run by CMS. ONC relies on private sector testing and certification organizations and operates the program "as a third-party product conformity assessment scheme for health information technology (health IT) based on the principles of the International Standards Organization (ISO) and International Electrotechnical Commission (IEC) framework".

ONC launched the program in 2010 to support the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs/Meaningful Use) administered by CMS. It has since expanded to other programs and beyond an EHR focus.

There have been three "editions" of certification criteria, with the 2015 edition required for CMS incentive programs as of 2019 (initially, it was to be required by 2018). Each edition has included more robust interoperability requirements, with 2015 notable for its requirements for an open API (with transparent access information) and a new Common Clinical Data Set (CCDS).

Current criteria and detailed test methods are on ONC's certification website, with many focusing on interoperability, including vocabulary and code sets, data definitions, and data transport.[34] ONC also provides access to tools for developers and end users to test conformance with standards, in many cases using tools developed by NIST.[35] ONC is also moving to shift testing tools from the federal government to the private sector[36]. Notably, ONC has released the *inferno* testing suite focused on the HL7 FHIR® standard, although this standard is not yet required[‡] for use in the open APIs in certified EHRs[37]. ONC also makes available a number of technical resources.[38]

Certified products are listed on the ONC Certified Health IT Product List (CHPL).[39] The CHPL provides detailed information on the certified elements of products that have received ONC certification. It calls out products that have been certified to the API criteria and enables users to obtain relevant technical and access information for these APIs, including which APIs use the HL7 FHIR® standard.[40]

With passage of the Cures Act, ONC is expected to update current certification requirements in a proposed rule expected in early 2019 to focus on product and company-level adherence to requirements for real-world testing, use of open APIs, and no information blocking.[41]

The ONC certification program, especially its interoperability-focused criteria, has played an important role in enabling wide availability of standardized products and technologies that enhance interoperability. It is notable for the collaborative development of test tools to assess conformance with applicable industry standards. The wide availability and use of the 2015 edition should enhance interoperability, including use of API-based exchange for patient access to their data. At the same time, there is a concern that the

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[‡] ONC is expected to propose use of HL7 FHIR® in forthcoming (early 2019) certification criteria.

program, grounded in a statutory and regulatory framework, cannot keep up with market-driven technology evolution and in its broad scope, and focus on measurement of conformance with CMS criteria, has sometimes hindered innovation.[42]

5. 21st Century Cures and Information Blocking

ONC worked with the HHS Office of the Inspector General on a forthcoming (February 2019) proposed rule that will address, in part, how to implement interoperability and information blocking provisions of the Cures Act discussed elsewhere in this brief.

Implementation of information blocking prohibitions, including specification of "reasonable and necessary" practices that could otherwise be prohibited, will have a profound impact on private and public-sector approaches to interoperability, including investments, policies and practices, and compliance approaches and associated costs.

6. Interoperability Proving Ground

The ONC Interoperability Proving Ground (IPG) is an "open, community platform" designed to showcase interoperability projects occurring in the U.S. and globally.[43]

7. Challenges

ONC has hosted various challenges[44] focused on new or emerging technology approaches, such as patient matching, API access, and data provenance.

8. Synch for Science/Synch for Genes

ONC has been working with National Institutes of Health (NIH), on the *Synch for Science* and *Synch for Genes*[45] programs. These data sharing programs support the Precision Medicine Initiative (PMI) and its *All of Us* Research Program.[46] This work includes the one million volunteers who will be donating physical, genomic, and electronic health record (EHR) -based clinical data to the *All of Us* Research Program. *Sync for Genes*, focused on increased genomic data sharing as part of the PMI, is using genomics specifications refined as part of the HL7 FHIR® standard.[47]

9. Pledges

In 2016, ONC sponsored a stakeholder interoperability pledge.[48] The pledge was signed by "[v]endors who provide 90 percent of hospital electronic health records used nationwide; the top five largest health systems in the nation and, in total, health care systems providing patient care in 46 states; and more than a dozen leading health care provider, hospital, technology, and consumer advocacy groups." It had three components:

- *Consumer Access*: To help consumers easily and securely access their electronic health information, direct it to any desired location, learn how their information can be shared and used, and be assured that this information will be effectively and safely used to benefit their health and that of their community.

- *No Blocking/Ensuring Transparency*: To help providers share individuals' health information for care with other providers and their patients whenever permitted by

law, and not block electronic health information (defined as knowingly and unreasonably interfering with information sharing).

- *Standards*: Implement federally recognized, national interoperability standards, policies, guidance, and practices for electronic health information, and adopt best practices including those related to privacy and security.

10. Consumer Information

ONC has issued resources aimed at consumers indicating how they can access their health information. In April 2018, it released an online interactive tool, *The Guide to Getting & Using Your Health Records* [49] "for patients, parents, and caregivers who want to get their health records". This tool focused on legal (e.g., HIPAA right of access), technical (e.g., patient portal and apps), and procedural (e.g., how to review your record for errors) aspects of access to one's medical records. It is organized in three parts:

- *Get it* — A step by step guide to getting your health record

- *Check it* — Tips for finding and fixing mistakes in your health record

- *Use it* — How to use, share, and manage your health record

Consumer access to data, especially as enabled legally under HIPAA and technically via patient portals and API-enabled apps, will be the dominant theme and driver for expanded interoperability and new business and technology models of "data liberation". This model has the potential to drive major investments by very large, non-healthcare-specific technology companies. A key challenge is how this focus will also meet needs of clinicians and healthcare organizations, across the care continuum, to have access to patient healthcare data for safer and more effective care. This issue is pressing as providers are the dominant economic buyers of healthcare IT, especially for the traditional healthcare IT industry.

Centers for Medicare and Medicaid Services (CMS)

1. MyHealthEData

The Administration has launched the *MyHealthEData* [50] initiative, which aims to empower patients by ensuring that they control their healthcare data and can decide how it will be used, while keeping that information safe and secure. This federal government-wide initiative is led by the White House Office of American Innovation with participation from the U.S. Department of Health and Human Services (HHS) – including CMS, ONC, and the National Institutes of Health (NIH), as well as the Department of Veterans Affairs (VA). It is intended "to break down the barriers that prevent patients from having electronic access and true control of their own health records from the device or application of their choice. This effort will approach the issue of healthcare data from the patient's perspective."

2. Blue Button 2.0

As part of *MyHealthEData*, CMS has launched Medicare's *Blue Button 2.0*,[51] which is intended to "significantly improve the Medicare beneficiary experience by providing them with their claims data in a universal and secure digital format". Blue Button 2.0 is an API that provides access to four years of Medicare Part A, B and D data for 53 million Medicare beneficiaries. This data includes type of Medicare coverage, drug prescriptions, primary care treatment and cost. Following current trends, Blue Button 2.0 uses the HL7 FHIR® standard for beneficiary data and the OAuth 2.0 standard for beneficiary authorization.

CMS expects that developers will create apps that provide patients access to their data via the Blue Button 2.0 API.[52] In its initial announcement in conjunction with HIMSS 2018, CMS indicated that it had recruited over 100 organizations to join the Blue Button 2.0 developer preview program.[53] It also stated notably that it will be "re-examining its expectations for Medicare Advantage plans and qualified health plans (QHPs) offered through the federally facilitated exchanges, and calling on all health insurers to release their data. CMS believes that the private plans that contract through Medicare Advantage and the exchanges should provide the same benefit that is being provided through Medicare's Blue Button 2.0."

> *MyHealthEData and Blue Button 2.0 open up a new chapter in federal government efforts to expand interoperability. By their nature, they have a large payer-driven component, whether via access to payer-held data as with Blue Button 2.0 or through incentives and requirements on providers in the payment and incentive programs described below. It is noteworthy that CMS is seeking to use its leverage on state and private-sector plans to expand the reach of this initiative.*

3. EHR Incentive Program (Meaningful Use)

The CMS Medicare and Medicaid EHR Incentive Program[54] (known as Meaningful Use - MU), has key elements to advance interoperability. These include objectives and measures focused on interoperability and provider obligations to possess and use Certified EHR Technology (CEHRT), which has ONC-certified capabilities for EHRs and other Health IT.

This program has increasingly focused on certified *data content* (e.g., the C-CDA "document" standard and the CCDS) rather than requiring provider use of certified data *transport* (e.g., the Direct Protocol). It also emphasizes patient access to data via the *View Download, Transmit* (VDT) capability, and with Stage 3, patient right of access to data via open APIs.[55] The program also includes public health interoperability (e.g., submission to registries) and quality measure interoperability.

As the incentive program progressed over the years, CMS, responding to provider feedback, made interoperability requirements both more of a focus and less prescriptive. For Medicare, this program ended with the 2016 payment year for Eligible Professionals (EPs), who are now Eligible Clinicians under the Medicare Quality Payment Program (QPP) (see below).

Stage 3 of the program for Medicare was revised to focus on interoperability, with six objectives and associated measures for hospitals (Medicaid MU for hospitals and eligible professionals (EPs) has two additional objectives, CPOE and Clinical Decision Support):

1. Protect electronic protected health information (ePHI)

2. ePrescribing

3. Patient Electronic Access

4. Coordination of Care

5. Health Information Exchange

6. Public Health Reporting

For Medicaid MU for EPs, as with hospitals, six out of eight objectives are focused on aspects of interoperability.[56]

At HIMSS 2018, CMS Administrator Seema Verma announced that CMS would propose major changes to the MU program as part of the then forthcoming 2019 payment year proposed rules.[57]

> *"CMS will be announcing a complete overhaul of the Meaningful Use program for hospitals, and the Advancing Care Information performance category of the Quality Payment Program. Ensuring the security of healthcare data will be an absolute requirement in order to avoid negative payment adjustments or to receive an incentive payment. Our new direction will not only reduce time and costs, but will also be laser focused on increased interoperability and giving patients access to their data across all of our programs.*
>
> *Last year, CMS finalized requirements for certain programs that providers begin using 2015 Edition certified EHR technology starting in 2019. This version ensures that systems will be able to share information with patients and care teams via open application programming interfaces – or APIs, so patients can easily take their data to other providers and can give access to their data to app developers. CMS believes that the future of health care data interoperability centers on the development and implementation of open APIs."*

See below on Promoting Interoperability Programs for details on this overhaul.

4. Promoting Interoperability Programs

On April 24, CMS released its annual hospital payment program proposed rule[58]. The proposed rule detailed interoperability-focused changes to the EHR Incentive Program and to the Advancing Care Information (ACI) portion of MIPS. To underscore the focus on interoperability also reflected in its *MyHealthEData* and *Blue Button 2.0* programs, CMS renamed these programs *Promoting Interoperability Programs*. The Medicare physician proposed rule was released in June and proposed to adapt these changes to Quality Payment Program for 2019 and beyond.

CMS reaffirmed that 2015 edition CEHRT, with its enhanced interoperability capabilities, including open APIs and the Common Clinical Data Set (CCDS), must be used starting in 2019. It also made other changes to 2019 program requirements to support interoperability:

- Adopting four interoperability-focused objectives and six scored measures (from 16);

- Consolidation or removal of some Stage 3 interoperability objectives and measures;

- New performance-based scoring methodology moving away from thresholds;

- EHR reporting periods in 2019 and 2020 as minimum of any continuous 90-days in a calendar year (reducing the incentive for active exchange relative to a full year);

- Public comment was sought on potential new measures for *Health Information Exchange Across the Care Continuum*, in which a hospital would send or receive electronic summary of care records with non-hospital providers; and

- The number of required hospital quality measures fell from 16 to 8 for 2020.

For interoperability-focused measures, notable aspects are:

- Elimination of *View, Download, or Transmit* (patient use) and *Secure Messaging;*

- *Send a Summary of Care* was renamed *Support Electronic Referral Loops by Sending Health Information;*

- More flexibility on what data must be sent to another provider – CMS proposed that hospitals can use any C-CDA template to meet the HIE measures;

- Remove *Request/Accept Summary of Care* and *Clinical Information Reconciliation,* described as challenging to measure, burdensome, and redundant;

- Proposed a new HIE Measure: *Support Electronic Referral Loops by Receiving and Incorporating Health Information* that builds on and replaces the existing *Request/ Accept Summary of Care* and *Clinical Information Reconciliation* measures;

  o Intended to reduce measurement burden with focus on electronic reconciliation using CEHRT of received electronic summaries of care (rather than measuring the extent to which summaries are received electronically)

  o CMS asked if revised EHR measurement certification/recertification is needed

  o Note that this change appears to reduce program-driven incentives to query for or seek external electronic patient records

- Proposed new *Provider to Patient Exchange* measure *Provide Patient Access* measure to *Provide Patients Electronic Access to Their Health Information;* and

  o This is the renamed Stage 3 *Provide Patient Access* measure

  o Eliminated *Patient Education* and *Care Coordination* measures, including requirements to measure patients' actions to access their information (versus provider making such information available); *Patient Generated Health Data; Patient-Specific Education; Secure Messaging;* and *View, Download, or Transmit* (capability still required but not patient action to use it)

- Revisions to public health and registry reporting and request for comments to eventually eliminate these measures from PIP.

CMS asked for comment on creating new *priority health IT activities* that would be alternatives to traditional incentive program measures, for example participation in the Trusted Exchange Framework and Common Agreement (TEFCA) could count for credit within the HIE objective instead of reporting on measures. Another activity could be specified API access (although it is unclear how the proposal differed from current API requirements). A final activity could enable a hospital to participate in a pilot, and eventually implement in production, an API based on the forthcoming FHIR® standard update to allow population level data (i.e., "bulk data") access through an API instead of reporting on Public Health and Clinical Data Exchange measures. CMS asks for suggestions for other activities. In its Final Rule, released on August 2, 2018, CMS did not indicate any decisions on such a change. [59]

The proposed rule also contained a Request for Information on "positive solutions to better achieve interoperability or the sharing of healthcare data between providers". Citing the forthcoming ONC TEFCA, CMS sought feedback on revising hospital Conditions of Participation (CoP) for interoperability, including requirements that:

1. Hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically;

2. Hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and

3. Hospitals make certain information available to patients or a specified third-party application (for example, discharge instructions) via electronic means if requested.

CMS also asked for comment on several questions, including:

- If CMS were to propose a new CoP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in the Cures Act?

- Should CMS propose new CoPs for hospitals and other providers and suppliers to ensure a patient's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden?

- Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding access as well as interoperability?

- Are new or revised CMS CoPs for interoperability and electronic exchange of health information needed to ensure patients/residents and their providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, HIPAA, and implementation of relevant policies in the 21st Century Cures Act?

- What would be a reasonable implementation timeframe for compliance with new or revised CoPs?

- Do stakeholders believe that new or revised CMS CoPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

CMS concluded this ambitious and sweeping line of questions by indicating that it wants "to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers". It cited the role MyHealthEData and Blue Button 2.0 in enhancing such communication and highlights ways that hospitals could use these tools, such as through "health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions."

CMS invited ideas on how best to "accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients". CMS asked especially about "fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records". CMS also sought comments on health IT adoption and interoperability for providers and suppliers that were ineligible for EHR Incentive programs.

CMS issued its final rule on August 2 with interoperability-relevant proposals adopted almost entirely as proposed.[60]

5. Quality Payment Program (QPP) – Medicare Incentive Payment System (MIPS)

Starting with the 2017 payment year, MIPS replaced clinician-focused Medicare payment incentive programs—MU, PQRS, and Value-based Modifier with the Quality Payment Program[61] (QPP) and its two tracks, Advanced Payment Models (APM)[62] and the Medicare Incentive Payment System (MIPS).[63.] The MIPS Advancing Care Information (ACI)[64] component replaced MU. Although it had more optionality than MU, ACI also emphasized interoperability, with all of its measures focused in whole or large part on interoperability via ONC-certified technology. Its five "Base" measures (must be met to achieve any ACI score) are core interoperability capabilities.[65] Two of the three remaining MIPS categories, Quality and Improvement Activities also reward use of certified EHR technology.

The 2019 annual Medicare physician payment proposed rule[66] was released on July 12, 2018 and proposed to apply the PIP to MIPS ACI (renamed Promoting Interoperability—PI), while retaining state Medicaid MU for Eligible Professionals with some modifications intended to reduce provider burden (e.g., retaining low thresholds for measures dependent on patient actions and aligning Medicaid and Medicare quality measures). CMS proposed several changes to MIPS consistent with the changes proposed and finalized for hospitals, notably a greater focus on interoperability and patient access to data and revisions and simplifications to measures focused on accessing and reconciling data.

In the physician-focused proposed rule, unlike the hospital proposed rule, CMS did not seek comment on a shift to activity-based measures, presumably because MIPS already has an Improvement Activities category, but it did seek comments on creation of new multi-category measures cutting across different performance categories and allowing MIPS ECs to report once for credit in three categories (e.g., one measure that would build on elements of the proposed Promoting Interoperability measure, Support Electronic Referral Loops by Sending Health Information, the improvement activity, Implementation of Use of Specialist Reports Back to Referring Clinician or Group to Close Referral Loop, and the quality measure, Closing the Referral Loop: Receipt of Specialist Report.).

In the physician payment rule, CMS also proposed major changes to streamline coding and payment for Evaluation and Management (E/M) (e.g., visit and consultation) codes, seeking to reduce administrative burden and improve payment accuracy for E/M visits. Many observers have concluded that the current E/M codes and associated documentation guidelines have increased burden and reduced usability associated with EHRs. These changes could have important changes for interoperability by refining and reducing documentation exchanged with providers and patients.

The final rule[67], released on November 1, largely adopted the CMS proposed changes to MIPS and ACI/PI, pushing off the payment-related E/M changes to 2021.

6. Quality Payment Program (QPP) – Advanced Payment Models (APMs)

There is a range of APMs[68]. Most require or create a strong business case for interoperability. ONC has indicated that most APMs require the use of Certified EHR Technology[69], with its significant interoperability capabilities, including support for APIs.

> *The EHR Incentive Program and QPP have increased health care digitization via greatly expanded hospital and clinician possession and use of certified EHRs with significant interoperability capabilities. At the same time, they have suffered from gaps between policy desires for interoperability and lack of a powerful business case, provider pushback against some interoperability requirements, concerns with a lack of usability, and the absence of a mature supporting interoperability-focused infrastructure (e.g., Direct address directories and sustainable Health Information Exchanges—HIEs). The CMS transformation of these programs into Promoting Interoperability heralds a major shift in the federal interoperability strategy, including CMS' heighted role in driving the federal interoperability agenda.*

7. State Medicaid Support

In 2016, CMS, with support from ONC, issued a letter to State Medicaid Directors providing guidance on how federal administrative matching funds at the 90 percent rate could be used for state activities to promote electronic health information exchange and encourage the adoption of certified EHR technology by Medicaid providers who were not eligible for the Medicare and Medicaid EHR Incentive Programs.[70] By 2016, CMS, with support from the states, had invested approximately $425 million in state Medicaid systems in this area since the start of the program, with $350 million directed to health information exchange.[71]

8. Interoperability and Patient Access

CMS has developed a proposed rule titled "Interoperability and Patient Access," expected for released in the first quarter of 2019.[72] The description at the White House Office of Management and Budget (OMB) states that "[t]o support this Administration's goals of interoperability, as well as the vision of the 21st Century Cures Act and E.O. 13813, this rule proposes policy changes to move the health care industry toward a more accessible and interoperable health care ecosystem. Also, this rule signals our dedication to solving a significant and persistent issue in the health care marketplace." Industry speculation is that this proposed rule will focus on expanded payer provision of API-based access to patients' data, similar to the CMS Blue Button 2.0 initiative and perhaps other new requirements and initiatives.

HHS Office for Civil Rights (OCR)

1. Patient Right of Access

The U.S. Department of Health and Human Service Office for Civil Rights (OCR) enforces HIPAA data access requirements. It has issued recent guidance on patients' right of access to their electronic health data under HIPAA.[73] The OCR website has resources focused on health IT and a portal for app developers.[74] ONC has also issued materials on this patient access reflecting HIPAA regulations and OCR guidance.[75] Patients' right of access, especially to direct health information to another organization, even if that organization is not a HIPAA-covered entity, has become an important element of recent initiatives focused on consumer-directed health information exchange.[76]

According to OCR, "[t]he Privacy Rule generally requires HIPAA covered entities (health plans and most health care providers) to provide individuals, upon request, with access to the protected health information (PHI) about them in one or more "designated record sets" maintained by or for the covered entity. This includes the right to . . . direct the covered entity to transmit a copy to a designated person or entity of the individual's choice."[77] OCR has issued FAQs that detail scenarios under which the right of access can be met via health IT, including asking that data be sent to a third party.[78] For example:

> "A patient requests in writing that her ob-gyn digitally transmit records of her latest pre-natal visit to a new pregnancy self-care app that she has on her mobile phone. The ob-gyn's EHR has the ready capability to establish the connection in a manner that does not present an unacceptable level of security risk to the PHI in the EHR or other of the ob-gyn's systems, based on the ob-gyn's Security Rule risk analysis."

To help facilitate this emerging route of health data exchange, the American Health Information Management Association (AHIMA) recently released a Standard Education Request for Information Form, building on these ONC guidance[79].

> As indicated above, the HIPAA patient right of access will be a major driver of patient-centric interoperability, focused primarily but not exclusively on API-enabled apps.

Veterans Administration (VA)

The VA announced an API-focused initiative at HIMSS 2018, at which then VA Secretary David Shulkin encouraged providers to pledge to work with VA to accelerate mapping of health data to industry standards, including HL7 FHIR®. This initiative includes VA's Open Application Programming Interface Pledge[80] (API), which commits that VA "will provide API access to developers for Veteran-designated mobile and web-based apps, clinician-designated applications for those who serve them and Choice Act partners responsible for coordinating their care via "bulk" access".

The VA also announced the "beta" version of Lighthouse Lab[81], a computer platform offering developers access to tools for creating mobile and web applications that will help veterans better manage their care, services and benefits. VA will begin building a Lighthouse Lab developer community. Participation will include testing APIs, building documentation, developing governance standards and testing workflows. The VA is also very focused on interoperability in its contract to replace its current EHR system.[82]

> VA efforts could exert a major influence on interoperability, both through the impacts of its requirements and investments as it replaces its EHR and through requirements for interoperability with non-VA community-based clinicians and providers.

National Institute of Standards and Technology (NIST)

The National Institute of Standards and Technology (NIST) is part of the U.S. Department of Commerce. It provides significant support for both the federal government and the private sector in terms of health IT standards development, identification, and testing.[83] For interoperability, NIST focuses on standards-related testing, with an emphasis on standards for the CMS meaningful use/PIP[84] and QPP programs. NIST provides access to a variety of testing tools[85] and information on health IT standards[86].

> Although NIST generally does not develop standards (which are primarily developed by private sector standards developing organizations – SDOs), its work on testing methods and tools has been an essential element of U.S. interoperability progress and can provide important support for future public and privates sector interoperability initiatives.

U.S. Food and Drug Administration (FDA)

The U.S. Food and Drug Administration has long focused on medical device interoperability[87], seeing such interoperability as integral to device safety. It has issued interoperability-focused guidance documents[88] and identified FDA "Recognized Consensus Standards".[89]

HHS Office of the Inspector General (OIG)

The HHS OIG enforces the information blocking provisions of the Cures Act. Enforcement is, in general, on hold, pending regulatory definition of "reasonable and necessary" practices that could otherwise be considered information blocking.[90]

> *As indicated above, enforcement of information blocking prohibitions will have a profound impact on private and public-sector approaches to interoperability, including investments, policies and practices, and compliance approaches and associated costs.*

Agency for Healthcare Research and Quality (AHRQ)

As part of its Health IT portfolio[91], AHRQ has funded multiple interoperability projects[92].

> *Federally funded private sector research has played a major role in enhancing the art and science of health care interoperability.*

Private Sector

Testing

There has been a recent renewed interest in private sector interoperability testing models, with real-world testing a requirement established in the Cures Act and an interest in going beyond and even sunsetting[93] government-focused interoperability testing.

1. ConCert by HIMSS™

    ConCert by HIMSS™[94] is a comprehensive interoperability testing and certification program governed by HIMSS and built on work of the EHR|HIE Interoperability Workgroup and IHE USA. This program tests and certifies EHR and HIE vendors, focusing on interoperability and secure, reliable transfer of data within and across organizations and states.

2. HIMSS Immunization Integration Program

    Supported by CDC, the Immunization Integration Program (IIP)[95] is a collaborative effort of HIMSS, Drummond Group and Chickasaw Health Consulting, LLC, to use EHRs and other clinical software to improve U.S. immunization rates.

Exchange Frameworks and Networks

There are a number of increasingly well-established health information exchange (HIE) networks and models that, in aggregate, cover a large proportion of U.S lives, involve very high numbers of transactions, have increasingly sought to collaborate and coordinate their efforts. Per congressional intent, the TEFCA is intended, in large part, to ensure that these and future initiatives can connect seamlessly in a trusted exchange environment. STOP

1. CommonWell Health Alliance

   CommonWell[96], with its service provider and members, has created a vendor-neutral data exchange platform. It is "committed to defining and promoting a national infrastructure with common standards and policies". Carequality and CommonWell recently announced general availability (GA) of connection between the two initiatives, an important move forward in the breadth and depth of standard-based health information exchange.[97] CommonWell has also announced in February 2019, a new CommonWell Connector™ program.[98] This program will assist health IT vendors and health care practitioners looking to connect to the nationwide CommonWell interoperability network. CommonWell members who provide integration platforms and services will be able to offer CommonWell services to their customers, including to provider organizations and end-user-oriented platforms like EHRs.

2. The Sequoia Project

   Through its initiatives and alliances, The Sequoia Project[99] brings together diverse participants to create practical solutions to health data exchange challenges. It focuses on improving physician and provider access to the data needed to support clinical decision making, patient safety, process improvement and payment. In 2018, The Sequoia Project updated its structure[100] and now has two distinct subsidiaries, eHealth Exchange and Carequality. With this reorganization, The Sequoia Project intends to continues its work "to bring together industry and government to transparently and inclusively develop solutions to the most pressing challenges of health data exchange". Current and planned topics include HL7 FHIR®, patient matching, information blocking, and supporting disaster response efforts (e.g., Patient Unified Lookup System for Emergencies (PULSE).

3. eHealth Exchange

   eHealth Exchange[101] was an initiative of The Sequoia Project that is now a Sequoia Project subsidiary. It grew out of the ONC-led Nationwide Health Information Network and is a group of federal agencies and non-federal organizations that came together to improve patient care, streamline disability benefit claims, and improve public health reporting through secure, trusted, and interoperable health information exchange.

4. Carequality Framework

   Carequality[102] a second subsidiary of The Sequoia Project, is a national-level, consensus-built, common interoperability framework to enable exchange between and among health data sharing networks. It brings together EHR vendors, record locator service (RLS)

providers and other types of existing networks from the private sector and government, to determine technical and policy agreements to enable data to flow between and among networks, platforms, and geographies, as the telecommunications industry did for linking cell phone networks. Carequality indicates that it is exchanging 14 million documents per month and that over 600,000 healthcare providers are using its trusted exchange framework to enable network-to-network connectivity. Carequality and CommonWell recently announced general availability (GA) of connection between the two initiatives.[103]

5. RSNA Image Share Validation

The Image Share Validation Program[104] is an initiative of The Sequoia Project that provides a conformity assessment program intended to set the "standard for consistency in the marketplace". It tests the compliance of vendor systems using quality standards determined most effective for accurate and efficient exchange of medical images.

6. Statewide Health Information Network for New York (SHIN-NY)

The Statewide Health Information Network for New York (SHIN-NY)[105] is a network connecting healthcare professionals across New York State. It connects eight regional networks, or Qualified Entities (QEs). This network model allows participating providers, with patient consent, to quickly access electronic health information and securely exchange data with any other participant in the state. SHIN-NY is sponsored by the New York eHealth Collaborative (NYeC), a non-profit organization working in partnership with the New York State Department of Health to improve healthcare by collaboratively leading, connecting, and integrating health information exchange (HIE) across New York State.

7. The Strategic Health Information Exchange Collaborative (SHIEC)

SHIEC[106] is a national collaborative representing health information exchanges (HIEs) and their strategic business and technology partners. It seeks to enable secure exchange of patient information to improve the quality, coordination, and cost-effectiveness of healthcare locally, regionally and nationally. SHIEC represents over 70 HIEs that together cover more than 200 million people across the United States.

8. Patient Centered Data Home

The Patient Centered Data Home[107] (PCDH) is a SHIEC initiative intended to be a cost-effective, scalable method of exchanging patient data among health information exchanges (HIEs). PCDH is based on triggering episode alerts that notify providers that a care event has occurred outside of the patient's "home" HIE and confirm the availability and the specific location of the clinical data, enabling providers to initiate a simple query to access real-time information across state and regional lines and the care continuum.

9. CARIN Alliance

The CARIN Alliance[108] is a bi-partisan, multi-sector membership alliance convened by former National Coordinator of Health IT David Brailer, former U.S. CTO Aneesh Chopra, and former HHS Secretary and Utah Governor Mike Leavitt, to unite industry leaders in

advancing adoption of *consumer-directed exchange* across the U.S. The alliance seeks to rapidly advance the ability for consumers and their authorized caregivers to easily get, use, and share their digital health information when, where, and how they want to achieve their goals. CARIN recently released a voluntary code of conduct for how entities not covered by HIPAA, such as third-party applications that can access data via APIs, can voluntarily handle health care data on behalf of consumers. CARIN has been influential and effective in advancing the vision of consumer-directed exchange, via the HIPAA patient right of access, through ONC 2015/FHIR-based APIs.

Standards Development Organizations and Initiatives

There are a number of standards development organizations (SDOs) and standards initiatives focused on health IT interoperability that have developed many standards covering multiple use cases and levels and aspects of interoperability. Although more standards work is (always) needed, much of this work is focused on developing constrained (i.e., less variability and optionality in usage*) implementation guides* and *specifications* of existing standards to enable effective interoperability for multiple use cases and under real-world and evolving implementation models and use cases.

1. HL7

    Health Level Seven[109] (HL7®) is one of several American National Standards Institute (ANSI) Accredited Standards Developing Organizations (SDOs) in healthcare. Most healthcare SDOs produce standards (also called specifications or protocols) for a domain, such as pharmacy, devices, imaging or insurance transactions. HL7 focuses on clinical and administrative data. It has multiple standards referenced in U.S. federal regulations[110] and has been producing healthcare data exchange and information modeling standards for over 20 years. Most of its standards are included in Version 2 (v 2) or Version 3 (v 3) Implementation Guides.[111]

    HL7 standards for the Clinical Document Architecture (CDS) and the Consolidated Clinical Data (C-CDA) have been prominent in recent interoperability standards and regulations, focusing on exchange of clinical "documents" containing standard data and data fields. The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies the structure and semantics of "clinical documents" for exchange between and among healthcare providers and patients.[112]

    Most recently, HL7, working with partners, has developed Fast Healthcare Interoperability Resources (FHIR®).[113] FHIR is a "new specification based on emerging industry approaches, but informed by years of lessons around requirements, successes and challenges gained through defining and implementing" various HL7 standards. *FHIR is the expected basis for the open APIs that many in the public and private sector anticipate will accelerate and transform health data exchange.*

    FHIR aims to simplify standards implementation and health IT developers seem to be very favorable on its use, which has been growing without specific certification requirements.

The FHIR building block for exchangeable content is a *resource*[114] (e.g., Procedure, EpisodeOfCare, Practitioner). The philosophy behind FHIR is to build a base set of resources that, either by themselves or when combined, satisfy most common use cases. FHIR resources aim to define the information contents and structure for the core information set that is shared by most implementations. Resources have a wide range of uses, from clinical content (e.g., care plans and diagnostic reports) to infrastructure. HL7 recently released version 4.0, which includes the first "normative" content. A number of implementation guides have been published to enable use of FHIR for specific purposes.[115] The U.S. Core Implementation Guide[116] is specifically designed to support the ONC Common Clinical Data Set (CCDS) and those CMS incentive and payment programs that rely on this data set.

2. The Argonaut Project

The Argonaut Project[117] is a private sector initiative to advance industry adoption of modern, open interoperability standards. The purpose of the Argonaut Project is to rapidly develop a first-generation HL7 FHIR-based API and Core Data Services specification to enable expanded information sharing for EHRs and other health IT based on Internet standards and architectural patterns and styles. The Argonaut work and specifications have been very important in the rapid development of FHIR implementation specifications and have moved into the regular HL7 specification development process.[118]

3. The Da Vinci Project

The goal of the Da Vinci[119] project, building on the Argonaut model, is to help payers and providers accelerate adoption of HL7® FHIR® as the standard to support and integrate value-based care (VBC) data exchange. Founding organizations are drawn from payers, providers and vendors committed to making value-based care a reality. The objective is to "minimize the development and deployment of unique solutions between trading partners (e.g. a payer and provider)". The focus is standards, implementation guides, and reference implementations. In late January 2018, stakeholders approved formation of Da Vinci and work began on initial use cases. The project focused on identifying payer/provider trading partners to develop and validate artifacts and tools for four use cases in 2018.

4. SMART on FHIR

SMART Health IT[120] is an open, standards-based platform that enables development of apps intended to "seamlessly and securely" run across the healthcare system. Using an EHR that supports the SMART standard, users can draw on this library of apps. The SMART platform is composed of open standards, open source tools for developers building apps and a public app gallery. Numerous SMART applications have been built and SMART applications are being used to support care at healthcare institutions. *Apple has implemented SMART on FHIR integration between EHRs and iPhones as of iOS 11.3, with many healthcare organizations supporting this API-based connectivity to patient iOS devices.*[121, 122]

SMART defines a health data layer that builds on FHIR API and resource definitions. SMART on FHIR[123] applies a set of "profiles" that provide developers with expectations about the

vocabularies that are used to express medications, problems, labs, and other clinical data. SMART on FHIR standards also outline an app authorization model based on the OAuth 2.0 standard, providing a key component that enables innovation while keeping patients and providers in control of their data. Finally, through SMART Genomics and SMART CDS Hooks, SMART is helping to define the next generation of FHIR®-based standards for the clinical use of genomic data and integration of clinical decision support into provider workflows.

5. Integrating the Healthcare Enterprise (IHE)

IHE[124] is an initiative by healthcare professionals and industry to improve the way computer systems in healthcare share information. IHE promotes *coordinated use* of established standards, such as DICOM[125] and HL7, to address specific clinical needs in support of optimal patient care. Systems developed in accordance with IHE communicate with one another better, are easier to implement, and enable care providers to use information more effectively. A number of IHE profiles[126] are in active use by various interoperability and exchange initiatives and referenced in the ONC ISA.

6. LOINC

LOINC[127] is a standard maintained by the Regenstrief Institute, which acts as a standards development organization (SDO). It provides a common language (identifiers, names, and codes) for identifying health measurements, observations, and documents. It serves as a "catalog of measurements", covering such items as lab tests, clinical measures like vital signs, standardized survey instruments, etc. LOINC is intended to enable "exchange and aggregation of clinical results for care delivery, outcomes management, and research by providing a set of universal codes and structured names to unambiguously identify things you can measure or observe". LOINC codes are used for many data elements in HL7 clinical documents, such as the C-CDA and for various FHIR® resources.[128]

7. SNOMED CT

SNOMED International is a not-for-profit organization that owns, administers and develops SNOMED CT. SNOMED CT[129] is a clinical terminology created to support clinical decision-making and analytics in software programs. It is referenced in ONC 2015 certification.

SNOMED CT is a clinically validated, semantically rich, controlled vocabulary. Used in software, SNOMED CT represents clinically relevant information "consistently, reliably and comprehensively". It supports development of comprehensive high-quality clinical content in health records and is a standardized way to represent clinical phrases. According to its developers, SNOMED CT:

- Is the most comprehensive, multilingual clinical healthcare terminology in the world;
- Is a resource with comprehensive, scientifically validated clinical content;
- Enables consistent, processable representation of clinical content in electronic health records;
- Is mapped to other international standards; and
- Is used in more than fifty countries.

8. Direct

Direct[130] is a standard originally developed by ONC, in contrast to most interoperability standards, which are developed by private-sector SDOs. It focuses on "pushing" health information to a known recipient. Direct is now maintained by the Direct Community[131] and is part of ONC 2015 certification. According to the ONC ISA[132], the Direct standard is based on the underlying standards used for modern email, SMTP and S/MIME. Successful use of Direct requires "trust" between the exchanging parties. According to ONC, the leading trust communities for Direct are DirectTrust (for provider messaging and consumer-mediated exchange) and NATE (for consumer-mediated exchange). The ISA notes that other standards can also be used for push (as opposed to query) exchange, including IHE-XDR.[133]

9. NCPDP

NCPDP[134] has developed multiple standards for the pharmacy industry. NCPDP standards have been included in various federal programs, including HIPAA, MMA, HITECH and Meaningful Use, Promoting Interoperability Programs and Quality Payment Programs, and state Prescription Drug Monitoring Programs (PDMPs).

10. DICOM

DICOM®—Digital Imaging and Communications in Medicine—is the international standard for medical images and related information. [135] DICOM® is recognized by the International Organization for Standardization as the ISO 12052 standard. It defines the formats for medical images that can be exchanged with the data and quality necessary for clinical use. DICOM is in almost every radiology, cardiology imaging, and radiotherapy device and increasingly in devices in other domains such as ophthalmology and dentistry. It is one of the most widely deployed healthcare messaging standards in the world. *DICOM use grew almost entirely as a result of the private sector rather than government requirements.*

11. CDISC

CDISC[136] develops and supports global, platform-independent data standards to enable information system interoperability to improve medical research and related fields.

Other Private-Sector Initiatives

1. Healthcare Services Platform Consortium (HSPC)

HSPC was founded in 2013 by Intermountain Healthcare, Louisiana State University and the Veteran's Administration to "refocus how healthcare applications are developed".[137] Over 270 contributors have joined—including leading healthcare and government organizations, healthcare technology vendors and investors supporting HSPC-centric portfolio companies. A provider-led consortium, HSPC is focused on developing a *healthcare services platform community* that "will enable an economy for interoperable applications in a SOA and knowledge-enabled model". It supports plug-and-play interoperability.

2. Integrated Health Model Initiative (IHMI)

The IHMI[138] is an American Medical Association (AMA)-sponsored collaborative effort that supports a continuous learning environment to enable interoperable technology solutions and care models that evolve with real-world use and feedback. IHMI incorporates meaningful data elements around function, state and patient goals. Current projects focus on hypertension management diabetes prevention, asthma functional status and patient goals social determinants of health

3. Digital Bridge

Digital Bridge[139], a collaboration between public health, delivery systems, and health IT vendors, is focused on enabling a bidirectional information flow between health care and public health. The initial focus is the electronic case report.

4. Center for Medical Interoperability

The Center for Medical Interoperability[140] is a 501(c)(3) cooperative research and development lab founded by health systems to simplify and advance data sharing among medical technologies and systems. It seeks to provide a centralized, vendor-neutral approach to performing technical work that enables person-centered care, testing and certifying devices and systems, and promoting the adoption of scalable solutions.

5. DirectTrust

DirectTrust[141] is a collaborative non-profit association of 121 health IT and provider organizations to support secure, interoperable health information exchange via the Direct message protocols. It has created a "trust framework" that extends use of Direct to over 106,000 health care organizations and over 1.5 million Direct addresses/accounts. This framework supports both provider-to-provider Direct exchange and bi-directional exchange between consumers/patients and their providers. Over 300 EHR and PHR vendors, and over 50 HIEs, participate in DirectTrust, enabling Direct exchange of health information to over half the professionals in the U.S. health care system.

6. National Association for Trusted Exchange (NATE)

The National Association for Trusted Exchange[142] (NATE) is a not-for-profit membership association focused on enabling trusted exchange among organizations and individuals with differing regulatory environments and exchange preferences. NATE leads or participates in a number of projects focused on exchange via multiple modes of transport, including Direct secure messaging and APIs. It issued the first release of *NATE's Blue Button for Consumers (NBB4C) Trust Bundle* in 2015. NATE is expanding beyond Direct messaging to other consumer-centric technologies (e.g., API-enabled exchange).

7. Electronic Healthcare Network Accreditation Commission (EHNAC)

Founded in 1993, the Electronic Healthcare Network Accreditation Commission (EHNAC)[143] is an independent, federally recognized, standards development organization and tax-exempt, 501(c)(6) non-profit accrediting body designed to improve transactional quality, operational efficiency and data security in healthcare. EHNAC has multiple accreditation programs

relevant to interoperability, including: Cloud-Enabled Services, Direct Trusted Agents, e-Prescribing, Health Information Exchanges, and Healthcare Networks.

8. Surescripts

Surescripts[144] is a collaborative of pharmacy-related organizations to "build a national network to connect clinicians, EHRs, hospitals, PBMs, pharmacies and technology vendors" It is focused on providing the value-added network infrastructure to enable e-prescribing and associated and adjacent services. It also supports clinical messaging and has established a record locator service (RLS) called Record Locator and Exchange[145] building on its established network and connections to providers.

9. Google

Google has launched a Cloud Healthcare API[146] intended to provide "a robust, scalable infrastructure solution to ingest and manage key healthcare data types—including HL7, FHIR and DICOM—and lets our customers use that data for analytics and machine learning in the cloud." The API is available in an early access release, but over the next year, Google plans to roll it out to more broadly. Google Apigee[147] already enables healthcare enterprises to manage and deploy FHIR APIs on top of their existing EHRs.

10. Apple

Apple announced *SMART on FHIR* integration between EHRs and the iPhone in iOS 11.3.[148] As of February 6, 2019, 204 healthcare organizations, some very large, have enabled connection of their EHRs to the iPhone via this API.[149]

11. Amazon

Amazon, which has been developing its healthcare strategy[150],[151] and is heavily invested in providing cloud services to healthcare vendors and providers[152], recently announced Amazon Comprehend Medical[153], a HIPAA-compliant *machine learning* service that allows developers to process unstructured clinical text and identify data like diagnosis, treatment received, drug dosage, and signs and symptoms. According to Amazon, this application helps providers, payers, researchers, and clinical trial investigators, along with health care IT, biotechnology, and pharmaceutical firms to improve clinical decision support, revenue cycle and clinical trials. *Of note, although the information used by this service would need to be digitized, it would not need to be structured or coded using standard terminologies.* This approach to data access, using APIs, natural language processing and cloud capabilities, is an alternate model to traditional and emerging interoperability solutions.

12. Microsoft

Microsoft continues to be engaged in healthcare IT, having established a new Microsoft Healthcare group and hiring one of the leads in SMART on FHIR to join this group. As with other major technology companies moving into healthcare, Microsoft envisions a cloud-based ecosystem benefitting from data liquidity.[154],[155]

INTEROPERABILITY LEGISLATION AND REGULATIONS

HITECH

The American Recovery and Reinvestment Act of 2009 (ARRA)[156] has extensive health IT provisions in Title XIII of Division A and Title IV of Division B, together referred to as the "Health Information Technology for Economic and Clinical Health Act" (HITECH). HITECH had only two references to the term "interoperability," "[p]romotion of the interoperability of clinical data repositories or registries" (Section 13301) and NIST funding of research on "software that improves interoperability and connectivity among health information systems" (Section 13202).

HITECH does, however, focus on *exchange* of electronic health information. For example, the definition of a *Qualified Electronic Health Record* in Section 3000 includes the ability to "'(iv) to exchange electronic health information with, and integrate such information from other sources." Elsewhere, HITECH established the EHR Incentive Program and codified ONC in statute. It also created the HIT Policy and Standards Committees and called for the Secretary of HHS to develop a health IT Certification Program. Part of the purpose of ONC in Section 30001 is "'(6) improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information. . .".

One of the duties of ONC was to develop an annual Health IT Strategic Plan that included: "specific objectives, milestones, and metrics with respect to the following: "(i) The electronic exchange and use of health information and the enterprise integration of such information." ONC was also to "establish a governance mechanism for the nationwide health information network." The HIT Policy Committee established in Section 3002 and the HIT Standards Committee established in Section 3003 had several responsibilities regarding health information exchange (as a noun and a verb). Section 13301 called on the Secretary to "invest in the infrastructure necessary to allow for and promote the electronic exchange and use of health information for each individual in the United States. . .".

Title IV established the EHR Incentive Program, creating incentives for "Adoption and Meaningful Use of Certified EHR Technology" (CEHRT). *CEHRT*, through incorporation by reference of *Qualified EHRs*, included the ability to "'(iv) to exchange electronic health information with, and integrate such information from other sources" in its core definition.

Section 13113(a) called on the Secretary to submit annual reports to Congress on "specific actions that have been taken by the federal government and private entities to facilitate the adoption of a nationwide system for the electronic use and exchange of health information . . .". The first such report was submitted on January 17, 2012 with updates in later years. The most recent report, for 2018, was issued in January 2019. It provides a somewhat gloomy assessment of the current state of interoperability and associated barriers while highlighting the promise of public and private sector actions underway, including expected wide use of open APIs.[157]

HITECH set in motion ONC and CMS programs related directly or indirectly to interoperability, including a multi-million-dollar program funding HIEs (organizations) in the states.[158] This latter program had mixed success and was plagued with issues of sustainability, shifting federal priorities, and lack of sufficient state and other resources to fully fund HIE efforts.

> *HITECH catalyzed and helped achieve accelerated digitization of U.S. healthcare, with a focus on certified EHR technology capable of and used for standards-based data exchange and an expanded state infrastructure of Health Information Exchanges. It achieved significant levels of digitization[159] but, as evidenced by later legislation and commentary[160], did not achieve hoped for levels of actual exchange and interoperability.*

MACRA

The Medicare Access and CHIP Reauthorization Act of 2015[161] (MACRA) is bipartisan legislation signed into law on April 16, 2015. MACRA eliminated the EHR Incentive Program for Medicare Eligible Professionals and combined multiple legacy Medicare clinician-focused quality programs into a new Merit Based Incentive Payments System (MIPS) and an alternate payment path based in alternative payment models (APMs). CMS implemented this program through a new Quality Payment Program (QPP).[162]

Achieving Widespread Interoperability

MACRA reflected where Congress and HHS had evolved on healthcare interoperability by 2015. Section 106(b) was titled "Promoting Interoperability of Electronic Health Record Systems". It stated that "[a]s a consequence of a significant Federal investment in the implementation of health information technology through the Medicare and Medicaid EHR incentive programs, Congress declares it a national objective to achieve widespread exchange of health information through interoperable certified EHR technology nationwide by December 31, 2018."

Widespread interoperability was defined as "interoperability between certified EHR technology systems employed by meaningful EHR users under the Medicare and Medicaid EHR incentive programs and other clinicians and health care providers on a nationwide basis". *Interoperability* was defined as "the ability of two or more health information systems or components to exchange clinical and other information and to use the information that has been exchanged using common standards as to provide access to longitudinal information for health care providers in order to facilitate coordinated care and improved patient outcomes". This definition focused on exchange, common standards, longitudinal information, and the purposes of care coordination and improved outcomes.

By July 1, 2016, the Secretary was to "establish metrics to be used to determine if and to the extent that the objective described in subparagraph (A) has been achieved". Notably, if the Secretary determines that this objective is not met by December 31, 2018, he or she must submit to Congress a report by December 31, 2019, that identifies barriers to this objective and that recommends actions that the Federal Government can take to achieve it. Such actions could include recommendations "(i) to adjust payments for not being meaningful EHR users

under the Medicare EHR incentive programs; and ii) for criteria for decertifying CEHRT products. In June 2016, ONC announced its measures[163]:

> Measure #1: Proportion of health care providers who are electronically engaging in the following core domains of interoperable exchange of health information: sending; receiving; finding (querying); and integrating information received from outside sources.

> Measure #2: Proportion of health care providers who report using the information that they electronically receive from outside providers and sources for clinical decision making.

The focus is on both *exchange and use* of data. ONC has stated that it will use existing nationally representative surveys of hospitals and office-based physicians to evaluate progress on interoperable exchange of health information from the provider perspective. It will also expand its scope of measurement to cover the broader care continuum and individuals, as well as impacts of health IT on health outcomes. Note that ONC has not yet established thresholds for determining whether nationwide interoperability has been achieved.

Information Blocking

MACRA also addressed *information blocking*. In Section 106(b)(2) it requires eligible professionals and hospitals to demonstrate (e.g., through MU attestation) that they have not "knowingly and willfully" taken action to limit or restrict the compatibility or interoperability of CEHRT. The first such attestations were required for the 2017 payment year. CMS regulations broadened their scope considerably from what MACRA had required[164]:

Statement 1: A health care provider must attest that they did not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT.

Statement 2: A health care provider must attest that they implemented technologies, standards, policies, practices, and agreements reasonably calculated to ensure, to the greatest extent practicable and permitted by law, that the CEHRT was, at all relevant times: 1. Connected in accordance with applicable law; 2. Compliant with all standards applicable to the exchange of information, including the standards, implementation specifications, and certification criteria adopted at 45 CFR Part 170; 3. Implemented in a manner that allowed for timely access by patients to their electronic health information (including the ability to view, download, and transmit this information); and 4. Implemented in a manner that allowed for the timely, secure, and trusted bidirectional exchange of structured electronic health information with other health care providers (as defined by 42 U.S.C. 300jj(3)), including unaffiliated providers, and with disparate CEHRT and health IT vendors.

Statement 3: A health care provider must attest that they responded in good faith and in a timely manner to requests to retrieve or exchange electronic health information, including from patients, health care providers (as defined by 42 U.S.C. 300jj (3)), and other persons, regardless of the requestor's affiliation or technology vendor.

In 2014, Congress also called for[165] ONC to issue a report on information blocking, which it did in 2015[166]. This well-done report set the stage for the statutory definition of information blocking in 21st Century Cures.

21st Century Cures

The 21st Century Cures Act[167] (Cures) was signed into law in December 2016. It brought together many of the trends that had emerged for interoperability and information blocking.

First, it added requirements on interoperability and information blocking to the ONC health IT certification program in Section 4002(a), requiring that HHS, by December 2017 (expected to be proposed in early 2019), add to conditions of certification that the developer:

> (i) does not take any action that constitutes information blocking as defined in section 3022(a);

> (ii) provides assurances satisfactory to the Secretary that such developer or entity, unless for legitimate purposes specified by the Secretary, will not take any action described in clause (i) or any other action that may inhibit the appropriate exchange, access, and use of electronic health information;

> (iii) does not prohibit or restrict communication regarding . . . the interoperability of the health information technology;

> (iv) has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort through the use of application programming interfaces or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws; and

> (v) has successfully tested the real world use of the technology for interoperability (as defined in section 3000) in the type of setting in which such technology would be marketed.

Second, Cures included interoperability in the range of EHR reporting criteria called for in Section 4002(c).

Third, Cures specified a very rigorous definition of interoperability, building on the IEEE definition. Section 4003(a) defines "Interoperability" as health IT that:

- "Enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user;

- Allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and

- Does not constitute information blocking."

Fourth, Section 4003(b) requires HHS to "develop or support a trusted exchange framework, including a common agreement among health information networks nationally." This requirement has become known as the Trusted Exchange Framework and Common Agreement (TEFCA) and is discussed in more detail earlier under ONC interoperability activities.

Finally, In Section 4004, the Cures Act defines *information blocking* as "a practice that:

- Is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information;

- If conducted by a health IT developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information; and

- If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information."

ONC actions and proposed regulations to implement various Cures Act provisions are discussed in the ONC section of this policy brief.

Congress remains very focused on timely and effective implementation of these Cures Act provisions. On October 31, 2017, the Senate Health, Education, Labor and Pensions (HELP) Committee held a hearing titled *Implementation of the 21st Century Cures Act: Achieving the Promise of Health Information Technology*[168]. Witnesses were from ONC, HHS OIG, and CMS. Committee members were impatient[169] regarding implementation progress and very focused on the need for progress on the new trusted exchange framework and common agreement (TEFCA), information blocking enforcement, and reduction of provider burden. The House committees of jurisdiction, notably Energy and Commerce, are also closely monitoring Cures Health IT implementation; an Energy and Commerce hearing was held in December 2018.[170]

ONC Regulations

ONC Certification

ONC has issued three editions of its health IT certification program, the most recent is the *2015 edition*, published in October 2015. This edition made a number of interoperability capability and standards enhancements, notably the requirement that Base (the ONC defined minimum that is incorporated by reference into the CMS CEHRT definition) certification requirements include capabilities for open APIs.[171] The ONC regulations did not specific HL7 FHIR® for these APIs, as it was then an emerging standard, but most certified heath IT uses FHIR as the basis for open APIs (this criterion is likely to be updated in the future to reference FHIR). A recent ONC blog highlighted the extensive use of FHIR in CEHRT.[172]

New Proposed Rules Issued February 19, 2019

On February 11, 2019 HHS released proposed rules to support seamless and secure access, exchange, and use of electronic health information. The proposed rules are designed to increase innovation and competition by giving patients and their healthcare providers secure access to health information and new tools, allowing for more choice in care and treatment. It calls on the healthcare industry to adopt standardized APIs, which will help allow individuals to securely and easily access structured EHI using smartphone applications.[173]

The rules place a strong focus on a patient's ability to access their health information through a provision requiring that patients can electronically access all of their EHI (structured and/or unstructured) at no cost. Finally, to further support access and exchange of EHI, the proposed rule implements the information blocking provisions of the Cures Act. The rule proposes seven exceptions to the definition of information blocking. A summary of the proposed rule will be added to this brief in February 2019. [174]

CMS Regulations

EHR Incentive Program

Comprehensive major regulations for the EHR Incentive Program were issued in October 2015: *Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 Through 2017*[175]. This final rule with comment period specified the requirements that eligible professionals (EPs), eligible hospitals, and critical access hospitals (CAHs) must meet to qualify for Medicare and Medicaid electronic health record (EHR) incentive payments and avoid downward payment adjustments under the program. In addition, it changed the Medicare and Medicaid EHR Incentive Programs reporting period in 2015 to a 90-day period aligned with the calendar year. This rule also removed reporting requirements on measures that have become redundant, duplicative, or topped out (i.e., most score at the highest levels) from Medicare and Medicaid EHR Incentive Programs.

In addition, this rule made Stage 3 requirements optional in 2017 and required for all participants beginning in 2018. Pushing out the start of Stage 3 also moved out the timing for required use of the ONC-certified open API and other interoperability enhancements. In the FY 2018 Medicare hospital payment rule[176], CMS further delayed required use of Stage 3 and 2015 CEHRT to 2019, again enabling but not requiring using of these criteria and capabilities.

Quality Payment Program (QPP)

On November 4, 2016, CMS published the *Medicare Program; MIPS and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models* final rule with comment period[177]. This rule established MIPS as discussed above in more detail under the section on CMS interoperability-related programs. In November 2017, CMS issued the final FY/CY 2018 version of the QPP[178]. As with the EHR Incentive Program final rule, this final rule also delayed required use of the full MIPS provisions (analogous to Stage 3) and of the 2015 edition CEHRT, including the API provisions.

Promoting Interoperability Programs (PIP)

On April 24, CMS released its annual hospital payment program proposed rule[179]. The proposed rule detailed changes to the EHR Incentive Program and to the Advancing Care Information portion of MIPS, highlighting an increased focus on interoperability by renaming these programs as *Promoting Interoperability Programs* and reaffirming that the 2015 edition CEHRT, with its enhanced interoperability capabilities, including open APIs, must be used starting in 2019. It also proposed other changes to the 2019 program requirements to support interoperability. The proposed rule also contained a CMS Request for Information to obtain feedback on "positive solutions to better achieve interoperability or the sharing of healthcare data between providers". CMS requested feedback on revising hospital Conditions of Participation regarding interoperability. CMS issued its final rule on August 2 with interoperability-relevant proposals adopted almost entirely as proposed.[180]

The annual Medicare physician payment rule[181] was released on July 12, 2018 and proposed to apply the PIP approach to the Quality Payment Program MIPS ACI component (renamed Promoting Interoperability—PI), while retaining state Medicaid MU for Eligible Professionals with some modifications intended to reduce provider burden (e.g., maintain low performance thresholds for measures dependent on patient actions and aligning Medicaid and Medicare quality measures). CMS proposed several changes to MIPS consistent with the kinds of changes proposed and finalized for hospitals, notably a greater focus on interoperability and patient access to data and revisions and simplifications to measures focused on accessing and reconciling data. The final rule[182], released on November 1, largely adopted CMS proposed changes to MIPS and ACI/PI, pushing off the payment-related E/M changes to 2021.[183] More detail on these changes is in the CMS section of this policy brief.

New Proposed Rules Issued February 11, 2019

On February 11, 2019, CMS proposed policy changes supporting its MyHealthEData initiative to improve patient access and advance electronic data exchange and care coordination throughout the healthcare system. The proposed rule also outlined opportunities to make patient data more useful and transferable through open, secure, standardized, and machine-readable formats while reducing restrictive burdens on healthcare providers. In addition to the policy proposals, CMS released two Requests for Information (RFIs) to obtain feedback on interoperability and health IT adoption in Post-Acute Care (PAC) settings, and the role of patient matching in interoperability and improved patient care. A summary of the proposed rule will be added to this brief in February 2019.[184]

CURRENT STATE OF INTEROPERABILITY

There are limited and scattered data on the extent of interoperability and these available data are not as current as we would like. They also tend to be focused on specific use cases and on *capabilities* and *transactions* rather than *outcomes and impacts*. The April 2017 *ONC Proposed Interoperability Standards Measurement Framework* describes potential measurement approaches and data sources going forward.[185]

Hospitals

In 2008, only 9.4% of hospitals had at least a basic electronic health record (EHR). By 2015, 96% of hospitals used certified EHR technology.[186] Researchers have used data from the IT Supplement of the American Hospital Association (AHA) Annual Survey to assess dimensions of U.S hospital interoperability. These data first became available for 2014; 2015 and 20177 data have now been reported on and analyzed in scholarly and other publications.[187] Analysts have used the multiple years of AHA data to review levels and trends in national hospital interoperability across four domains: *finding, sending, receiving, and integrating* electronic patient information from outside providers.

The authors of one major study[188] using these data note that "[i]Integrating patient information is the key capability that separates interoperability from health information exchange (HIE): Interoperability requires that no manual effort is necessary to integrate information into the EHR". They reported year over year small increases, with 29.7% of hospitals engaged in all four of these domains in 2015, up from 24.5% the prior year. The two domains with the most progress were sending (up 8.1 percentage points) and receiving information (up 8.4 percentage points); there was no change in integrating systems. Hospitals' patient care-relevant use of data from outside healthcare organizations was lower; only 18.7% of the surveyed hospitals indicated that they "often" used these data.

The authors conclude that "hospitals' progress toward interoperability is slow and that progress is focused on moving information between hospitals, not on ensuring usability of information in clinical decisions". These findings and assessments track those of KLAS (see below), which sees the effective use of exchanged data as the real target.

Among hospitals that reported that they "rarely" or "never" used information received electronically from outside sources, the most commonly cited barrier (48.6%) was the fact that clinicians could not view outside information within the workflow of their EHR. Other barriers included "difficulty in integrating information into the EHR, not having the information available when needed, and not having it presented in a useful manner".

Several characteristics were significantly associated with hospitals that reported both availability and use of outside information. These include: a comprehensive EHR, being part of a health care system, and being part of a patient-centered medical home (but not an ACO). The authors also note that "policy efforts to expand the use of bundled payment should drive hospitals' demand for interoperability (specifically with long-term care providers) by providing a financial incentive for hospitals to be aware of the services delivered outside of their organizations".

The latest AHA report provides information through 2016-17.[189, 190] Send and Receive capabilities remained high and showed little change between 2015 and 2017. There were, however, notable increases in the ability to Find (query) data externally (52% to 61% from 2015 to 2017), Integrate data into the medical record (38% to 53%) and in engaging in all four domains of exchange (26% to 41%).

Physicians

Data on physician health data exchange is more limited than for hospitals. In 2008, only 16.9% of office-based physicians had at least a basic electronic health record (EHR). As of 2017, 79.7% of these physicians used certified EHR technology.[191] ONC has reported, using data from the CDC, that for office-based physicians in 2015, 38% electronically sent patient information to any providers outside their organization and 21% electronically sent summary of care records to sources outside their health system. [192] The numbers were higher for electronically sharing any patient health information with other providers, 39% in 2013 and 48% in 2015. For receiving information, 38% electronically received patient information from any providers outside their organization and 34% electronically found (queried) patient health information from sources outside their health system.

With respect to being able to integrate and use information, 32% of office-based physicians have necessary patient information electronically available from providers or sources outside their systems at the point of care and 31% could easily integrate (e.g., without manual entry) health information received electronically into their EHR in 2015.

Data on patient access to health IT were more promising. The percentage of office-based physicians whose patients could view online, download, or transmit information from their medical record nearly doubled between 2013 and 2015, from 33% to 65%, but the numbers tailed off in 2015 from View (63%), to Download (41%), to Transmit (19%).

Skilled Nursing Facilities

Interoperability in Skilled Nursing Facilities (SNF) is an important determinant of effective interoperability across the continuum of care. ONC has issued two Data Briefs on this issue, focusing on 2016 and 2017 data.[193, 194] The latest ONC brief presents key measures on EHR adoption and interoperability, looking at four domains of data exchange: send, receive, find, and integrate. It found that:

- A majority (66%) of SNFs used an EHR;
- 37% of SNFs used an EHR alone for electronic data exchange and 4% use both an EHR and a state or regional health information organization (HIO);
- 30% of SNFs electronically exchanged key clinical health information;
- Nearly two-thirds (48%) of SNFs had information electronically available from outside the SNF at point of care; and
- SNFs using an EHR, a Health Information Organization (HIO), and read-only access had outside patient health information available at the point of care more frequently than those using only an EHR.

KLAS

KLAS[195], an organization that evaluates health IT technology, also tracks interoperability progress, focusing on both product capabilities and the experience of healthcare organizations. Comprehensive data were reported in October 2017. KLAS reports are proprietary but summaries of the October 2017 report are in the trade press[196]. KLAS reviewed 420 healthcare

organizations and reported that the number of providers achieving what it calls "deep" interoperability has increased, although most do not report high levels of interoperability.

Deep interoperability is a high bar, but very consistent with the Cures and similar definitions. For KLAS, "[a]n organization is counted as having reached 'deep interoperability' if they indicate one of two optimal responses in all four interoperability stages. The deep interoperability rate refers to the percent of interviewed organizations within each vendor's customer base that (1) often or nearly always have access to needed data through any interoperable means; (2) are able to easily locate specific patient records or have them automatically presented to clinicians; (3) have the retrieved patient data fully integrated into the EHR's (electronic health records) native data fields or in a separate tab or section within the EHR; and (4) believe retrieved patient data often or nearly always benefits patient care to the extent that it should."

The 2017 KLAS report found **that the percentage of healthcare organizations reporting deep interoperability when sharing data with** disparate EHRs more than doubled from 6% on 2016 to 14% in 2017, with "reasonable access" at a higher but still low 28%. The highest deep interoperability for an EHR vendor was 23% in 2017. KLAS also found that, in general, health care organizations had more success sharing with other organizations using the same EHR. On average, such organizations had a 26% deep interoperability level. In a late 2018 report, KLAS focused on "Real Progress with Patient-Record Sharing via CommonWell and Carequality."[197]

eHealth Exchange

The eHealth Exchange[198] (eHX) began under ONC in 2008 as the Nationwide Health Information Network (NwHIN), the nation's first and largest public-private health data sharing network of its kind. This network, now a subsidiary of The Sequoia Project, is the primary way that federal agencies exchange health data with the private sector. Today, this network enables information to be exchanged for 120 million patients among four very large federal agencies (Department of Defense, Veterans Health Administration, Centers for Medicaid and Medicare, and Social Security Administration), 59 regional and state HIEs, 75% of U.S. hospitals, 70,000 medical groups, 8,300 pharmacies, 3,400 dialysis centers, and 120 million patients.[199] The Sequoia Project projects that about 100 million clinical document and quality measure transactions are exchanged every year by the eHX (Because of the federated nature of the eHealth Exchange, these metrics are self-reported.)

Carequality Framework

Carequality[200] provides a framework for exchange among existing HIE networks and different technology platforms. The first exchange under this framework was in July 2016. This framework allows a network to "implement once and connect universally" and its scope has increased since mid-2016 to include over 600,000 physicians across 35,000 clinics and 1,250 hospitals.[201] Carequality reports that the volume of clinical data exchanged accelerates every month, with over 2 million clinical documents exchanged in December 2017. By its own count, Carequality enables 50% of U.S. physicians to share beyond their own networks. With its recent connection to CommonWell[202], this upward trajectory is likely to continue.

CommonWell

CommonWell has not published usage data but provides up-to-date graphical information on its growing footprint of providers.[203]

ONC 2015 Edition CEHRT/Open APIs

The availability of EHRs certified to the ONC 2015 edition is a useful marker of product availability to support robust interoperability capabilities, especially open APIs. ONC has released a data "mash up" that provides very important and current data points.[204] [205]Although market share data are approximate, the data indicate that, as of November 2018, about 90% of both clinicians and hospitals have ONC 2015 edition CEHRT that is fully certified to the ONC Base requirements, which include open API certification, with several high market share products certified to nearly all of the Base requirements, including API requirements. 307 products have been certified to the 2015 API criteria as of February 2019, with the vast majority citing one of the most recent HL7 FHIR® standards.[206]

ePrescribing

Electronic prescribing (ePrescribing) has been a signal interoperability success story. Its growth has been driven by a combination of regulatory incentives/requirements and market demand. In its 2017 National Progress Report[207], Surescripts reports that 77% of prescriptions were electronic in 2016, with a growth in ePrescriptions from about 1 billion in 2013 to 1.74 billion in 2017. The overall percentage of prescribers prescribing electronically was 69%, up from 57% in 2015. In an early report, ONC reports, using Surescripts data, that by April 2014, 70% of physicians were e-prescribing using an EHR on the Surescripts network, a very large increase from 7% in December 2008 when the MIPAA legislation passed and from 24% from January 2011, when the Medicare and Medicaid EHR Incentive Programs began.[208]

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