



CENTER *for* MEDICAL
INTEROPERABILITY

June 22, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
US Department of Health and Human Services
Attention: CMS-1694-P
P.O. Box 8011,
Baltimore, MD 21244-1850

submitted electronically via: <http://www.regulations.gov>

RE: CMS-1694-P; Fiscal Year (FY) 2019 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long Term Acute Care Hospital (LTCH) Prospective Payment System Proposed Rule, and Request for Information

Dear Administrator Verma:

On behalf of the hospital and health system members of the Center for Medical Interoperability (CMI), we are pleased to offer comments to guide the future direction of the Promoting Interoperability Program and to respond to the Request for Information on Promoting Interoperability and Electronic Information Exchange. We applaud CMS, HHS and ONC for recognizing the need to improve existing programs and for their persistence in trying to tackle one of the most elusive problems of today's society, interoperability among health information technology solutions. CMS is uniquely positioned to create and incent a truly interoperable health data infrastructure and it should use its available levers to compel change and encourage rapid innovation across the marketplace. Renaming the Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs, *Promoting Interoperability*, is an apropos and powerful harbinger of the transformative action to follow, and The Center for Medical Interoperability stands ready to assist this approach and industry-wide transition.

CMI is a non-profit organization led by health systems with a vision to ***accelerate the seamless exchange of information to improve healthcare for all***. Modeled after other industry centralized labs, it serves as a national R&D lab and test & certification resource to address technical challenges related to healthcare data security, connectivity and interoperability. CMI's CEO-level Board of Directors identify healthcare industry technology problems that, when solved, will benefit the public good. CMI membership is limited to health systems, individuals and self-insured corporations but works with a variety of stakeholders, including medical device vendors, electronic health records companies, standards development organizations, and other entities, to

design and engineer the technical infrastructure that will enable data liquidity, interoperability and person-centered medical care.

We appreciate the opportunity to provide input during this critical step. Our response addresses the following sections and key questions:

VIII. D. 8. Promoting Interoperability Program Future Direction

What activities should CMS consider recognizing in lieu of reporting on objectives that would most effectively advance priorities for nationwide interoperability and spur innovation? What Principles should CMS employ to identify health IT activities?

XII. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid- Participating Providers and Suppliers

CMI recognizes that this transition is a long-term one, and it is unrealistic to expect participating health care providers and suppliers to comply with requirements and adopt systems that exceed their capability to support. That being said, if the US healthcare system expects to achieve its overarching goals of improved health care at lower costs, it is vitally important to create a sound long-term strategy and to invest in the right systems and infrastructure that will stand the test of time. CMI urges CMS, HHS and ONC to adopt and incorporate the principles discussed below when considering the future path and directives of the Promoting Interoperability Program.

Principles and Suggested Activities

While CMI applauds many of the changes proposed to the Medicare and Medicaid EHR Incentive Programs in an effort to eliminate redundancies, reduce administrative burden and streamline the quality reporting system, it encourages CMS to think beyond initiatives that produce incremental improvement in favor of supporting the creation of a national data interoperability infrastructure that supports long-term success. An understanding of the underlying principles that support an ideal health information exchange system is critical to planning for this future reality and identifying the right activities. CMI identifies the following principals for consideration: data liquidity, comprehensive interoperability, trust, connectivity, and person-centric access. In addition, CMI proposes the following activities for consideration (1) embrace medical interoperability platform architecture and (2) support a forum for industry alignment.

Principle: Data Liquidity

CMI recommends a major shift in the US health data exchange paradigm and understands that realizing the benefits of a value-based and learning health system will depend upon the utility of the framework for health information

technology and exchange. “Data Liquidity” is a core property of this framework. Once vital data is freed from previously controlled data system siloes and allowed to flow when and where it is needed, it can be contextualized and turned into valuable information that can then be analyzed to become useful and computable knowledge and wisdom. An understanding of this knowledge hierarchy allows CMI to create interoperable technical solutions that enable the type of ubiquitous data liquidity required to achieve desired endpoints of end users and healthcare delivery systems.

Principle: Comprehensive Interoperability

In order to provide the best care to patients and populations, our healthcare systems and marketplace require unprecedented access to trusted and secure health information. Access to data becomes essential as we migrate to new models of care that include outcomes-based reimbursement, personalized medicine and population health. Leading organizations recognize that sustainability and competitive advantage will be driven by their ability to deliver safe, efficient, and economical care and this cannot be accomplished without involving stakeholders and companies from in and outside of healthcare. Achieving true data liquidity requires health data to flow from the person, within an episode of care, across care settings and to become accessible to an innovation marketplace.

Most, if not all, interoperability efforts to date have been focused on network-based exchange of electronic medical record (EMR) data. While CMI is a strong advocate of these efforts, it believes that data liquidity and interoperability should not stop at the network level. It should be pervasive and comprehensive.

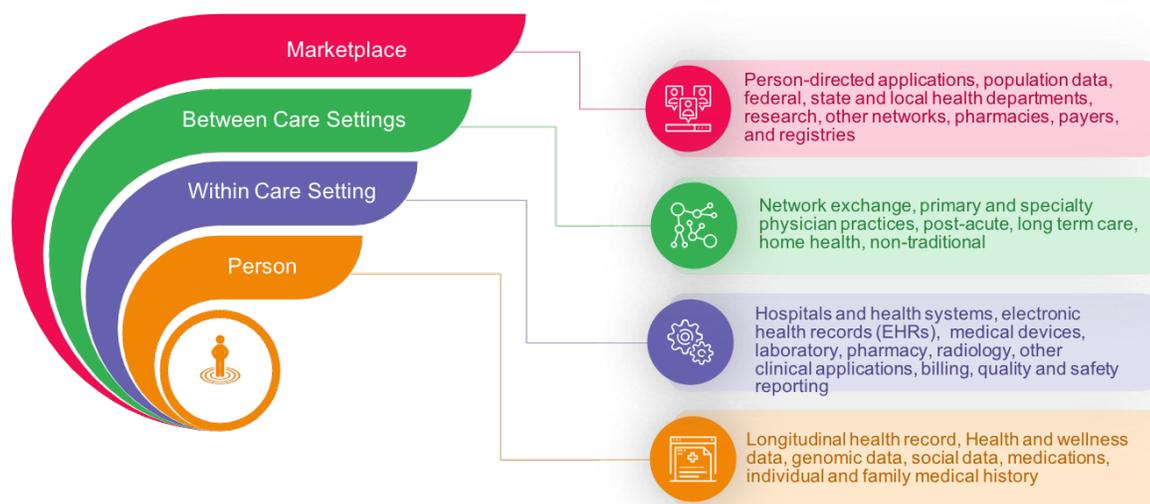
Comprehensive interoperability constitutes more than HIE or system-to-system data sharing; it refers to the ability to seamlessly and automatically deliver data when and where needed, safely and securely, and without political, technical, or financial blocking. When supported by the right trust framework, liberating data from medical devices, electronic medical records, enterprise applications, research databases and other sources of information will allow the health ecosystem unprecedented opportunities to meaningfully improve care, increase operational efficiency and lower costs.

To realize the full extent of these benefits, we must not stop with network-to-network data sharing. We must address the lack of standard, semantic, and specification alignment that is hindering data liquidity throughout the entire system of care and within all supporting technologies. Data should be able to flow seamlessly and securely at the episode of care as easily as it does across care settings, enterprise layers and systems. Designing a technical underpinning and

associated trust framework that supports this aim will require a much broader view and approach.

CMI has developed a framework to achieve comprehensive interoperability and data liquidity. Figure 1 is a graphical representation of the framework.

Figure 1: CMI View of Comprehensive Interoperability



CMI's first strategic priority is to address the lack of interoperability and data liquidity within the episodes of care, where the person/patient intersects the modalities of care (medical devices & solutions), and where clinical decision support is critical to patient safety and outcomes. It includes medical devices, EMRs, clinical decision support tools, and a medical interoperability platform. Ultimately, the data collected in the episode of care is consolidated and provided to the EMR and other clinical decision support applications.

Principle: Trust

Interoperability begins with and demands Trust. Hospitals and health systems consider cyber and other threats to connected medical devices to be one of the most significant risks to their businesses — this includes financial exposure and the potential for patient harm. CMI considers a condition precedent to comprehensive interoperability and data liquidity, and it is working to improve security and interface requirements by prioritizing connectivity, identity, authentication, encryption, and secure software updates. CMI is building security into its vendor-neutral platform, application programming interfaces (APIs) and apps, from the start, so that providers have a secure way to process an API

request without compromising their security tools. CMI is engaged with the majority of all medical device vendors and has published initial draft specifications supported by interoperability testing. CMI is also providing a Trusted Wireless Health reference architecture for hospitals as a foundational step to address the many challenges related to the use of the unlicensed Wi-Fi bands for consumer, enterprise and medical devices.

CMI strongly supports the 21st Century Cures legislation which calls for the ONC to work with the healthcare marketplace to achieve interoperability. CMI applauds the ONC's overall intent of the draft Trust Exchange Framework and Common Agreement (TEFCA) and recognizes that, if implemented broadly, it can help align health data exchange between networks using legacy EMR data, HIE networks and current approaches to data exchange and patient identification. While CMS may consider participation in TEFCA to be a health IT activity that could substitute for existing measures for the Health Information Exchange objective, it should not misconstrue HIE level exchange to constitute meaningful and comprehensive interoperability.

As the scope of TEFCA addresses "trust" at the network-level information exchange, it neglects the technologies and infrastructure beneath an EMR-centric network and does not provide robust or scalable direction to ensure trust and security in medical devices, systems and applications deployed within the continuum of care. Private sector initiatives must play an important role in filling the gaps left by the TEFCA, and healthcare leaders, private and public, must unite around a comprehensive approach to person-centered healthcare.

Principle: Connectivity

Data liquidity calls for all medical technologies using a standards-based interface and without undue financial burden to the hospital. Today, the adoption of standards-based interfaces is poor, at best, due to the gaps in standards and the poor adoption by vendors and hospitals. CMI is working with the medical device vendors to chart a course to fill those gaps and to migrate to a standards-based interface. Together, CMI works with industry vendors to develop syntactic and semantic interface specifications needed by health systems to seamlessly and securely connect their medical devices with their enterprise applications through a neutral, non-proprietary interoperability platform. The financial burden hospitals bear by having to pay for interfaces to and from proprietary systems is unacceptable and has resulted in less affluent hospitals, including many that serve a disproportionate share of CMS patients, having virtually no interoperability between medical devices and enterprise systems. Replacing the legacy device driver model with plug-and-play interoperability will address technical and economic barriers that impede the free-flow of data within the healthcare enterprise.

Principle: Person-Centric Access

There must be a way for an individual to consume, see and “own” their own information in an interoperable system that is agnostic to health system setting and provider type. Patients are tired of portals. Portals provide only a limited view of select proprietary and incomplete information and are just the “patient representation” of one system or provider’s record. Only a trusted, neutral and secure personal longitudinal record supported by a digital identity can provide an appropriate level of utility and control that individuals will need and require in order to benefit from true interoperability. CMI supports the creation of personal identification algorithms or identifiers to support data transmission, aggregation of longitudinal health data sets on behalf of the individual, and ensuring that APIs and network sharing approaches include a path for patient access to full data sets.

Suggested Activity: Embrace Medical Interoperability Platform Architecture

CMI believes that interoperability issues can be resolved only by establishing an overarching software architecture that supports the free flow of information on a vendor-neutral / non-proprietary platform that is operated like a utility with fair, effective funding across stakeholders. Once the technical solutions and medical modalities in the episodes of care are trusted and have standards-based interfaces, they will connect to a medical interoperability platform in a one-to-many, two-way, plug- and-play, standards-based and trusted manner. One-to-many means the ability to add a device without jeopardizing other devices. Two-way means the ability to send and receive data – leading to data liquidity within the clinical care setting. Plug-and-play refers to the ability to add or replace devices without human action – which will drive competition. Standards-based means adhering to interface specifications, and will reduce costs, drive competition and promote innovation. Lastly, everything on or in the platform, will be trusted.

CMI feels strongly that this platform requirements must be driven by the purchasers and users of health information. Hospitals and health systems and other large purchasers of healthcare technology and services, including CMS, should collectively use their buying power to align on the principles of platform architecture for data exchange. Benefits can be realized by all stakeholders. Right now, vendors often compete on the way that they present and process their information within their proprietary solutions. When technology vendors align on a common platform for interoperability, it will allow them to simplify and decouple their proprietary products by leveraging the signals that natively come from not only their product but all others. Standardizing the playing field allows technology vendors to move up the value chain, gain scale and to differentiate

themselves on how they analyze, package, and present that data rather than the current market capture.

Suggested Activity: Support a Forum for Industry Alignment

The Meaningful Use program efforts, to date, represent one of the largest investments in health care infrastructure ever made by the federal government. The criteria for Stage 1 and Stage 2 Meaningful Use, surpassing the 2013 goals set forth by HHS for EHR adoption achieved tremendous value in the digitization of health records. However, this program actually fell short of achieving meaningful use in any practical sense, without inclusion of comprehensive interoperability and data liquidity. Most patients still cannot gain electronic access to their health information, and rational access to EHRs for clinical care and biomedical research does not exist outside the boundaries of individual organizations. Although current efforts to define standards for EHRs and to certify HIT systems are useful, they lack a unifying software architecture to support broad interoperability across all medical technologies. Interoperability is best achieved through the development of a comprehensive, open architecture, which will require an investment in national infrastructure on equal scale with the previous stages of Meaningful Use.

CMS has the opportunity to make this investment now and drive adoption and interoperability by defining successive stages of Promoting Interoperability Program criteria that move progressively from the current closed box systems to an open software architecture. It is also important to recognize the market and leadership force that private industry must play in realizing this transformation. CMS, in conjunction with the private sector, should consider the establishment of an entity to align and focus the multiple activities related to comprehensive interoperability and data liquidity. While incredible pockets of work are underway, the lack of industry alignment will limit the success of any one activity. Such an entity would need to bring together all relevant stakeholders and relevant interoperability initiatives to ensure fundamental alignment on common principles. We note that similar models have been used to focus the healthcare industry on important topics of common national interest, such as the National Quality Forum. We believe that “Comprehensive Interoperability and Data Liquidity” requires a similar forum to guide the next 10 years of a Promoting Interoperability Program agenda. Such a forum would be necessary and complementary to CMS implementing appropriate levers, inclusive of Conditions of Participation, to drive industry adoption.

Healthcare delivery and its technology infrastructure are approaching a critical juncture. Standards development and EHR adoption over the past decades have laid a fertile ground for an era of data liquidity where key information flows across the care continuum – and across the life cycle – helping clinicians to make better decisions at the

right time for the right person. In the marketplace, it is also a critical time to ensure that competition among healthcare providers and technology vendors is focused on quality and value, rather than on exclusivity and proprietorship of data. CMS, HHS and ONC have the ability to become change agents in this journey, especially when combined with the right private industry leadership and market incentives.

CMS should embrace the Promoting Interoperability Program as an opportunity to break through the *status quo* and embark upon a transformative journey to create a truly interoperable health data infrastructure. CMS is uniquely positioned to create and incent the right technical underpinning for all of US healthcare, and it should use its available levers, including Conditions of Participation with the right roadmap in place, to compel change and encourage rapid innovation across the marketplace.

It is time to devote the nation's resources and attention to solving the issue that will make it possible to create the patient-centric health care system that we envision. The Center for Medical Interoperability stands ready to assist HHS, CMS and ONC with the process to progress from the current state of health care systems with limited interoperability to the future state of health care systems with fully interoperable systems. The learning health care system that we envision is not possible without interoperability, and we have an obligation to improve health care so future generations will have better lives. The time is now to realize the true potential of health information technology.

Thank you for your consideration. We welcome the opportunity to work with CMS, HHS, ONC and other stakeholders.

Sincerely,

Center for Medical Interoperability

A handwritten signature in black ink that reads "F.E. Cantwell". The signature is written in a cursive, slightly slanted style.

Ed Cantwell, President and CEO

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