



CENTER *for* **MEDICAL**
INTEROPERABILITY

September 27, 2019

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare and Medicaid Services
Attention: CMS-1715-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Request for Information (RFI) on Integration of Patient-Generated Health Data Into EHRs Using CEHRT; Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations; CMS-1715-P; RIN 0938-AT72

Submitted Electronically

Dear Administrator Verma:

Thank you for the opportunity to respond to the Request for Information (RFI) on Integration of Patient-Generated Health Data (PGHD) into electronic health records (EHRs) using certified electronic health record technology (CEHRT) from the Centers for Medicare and Medicaid Services' (CMS) proposed rule on the Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicaid Promoting Interoperability Program Requirements for Eligible Professionals; Establishment of an Ambulance Data Collection System; Updates to the Quality Payment Program; Medicare Enrollment of Opioid Treatment Programs and Enhancements to Provider Enrollment Regulations Concerning Improper Prescribing and Patient Harm; and Amendments to Physician Self-Referral Law Advisory Opinion Regulations. We are only responding to the RFI related to PGHD.

The Center for Medical Interoperability (C4MI) is a non-profit organization led by health systems with a mission to ***accelerate the seamless exchange of information to improve health care for all***. Modeled after centralized labs from other industries, C4MI serves as a cooperative research and development lab as well as a test and certification resource to address technical challenges related to comprehensive interoperability, data liquidity, and trust. C4MI's CEO-level board of directors identify health care industry technology problems that, when solved, will benefit the public good and the health care industry. C4MI membership is limited to health systems, individuals, and self-insured corporations, but we work with a variety of stakeholders, including medical device manufacturers, EHR vendors, standards development organizations, and others, to design and engineer the technical infrastructure that will enable comprehensive interoperability, data liquidity, and the trust needed to deliver person-centered medical care.

We believe that the delivery of health care in America can be vastly improved. In an increasingly digital age where data and technology have entered nearly every facet of our lives, the delivery of health care seems relatively unchanged. In most areas technology has enabled better experiences, and data availability has improved efficiency and outcomes. In health care, however, it seems that technology and data have increased both complexity and costs in an already unwieldy and expensive system.

What the healthcare industry needs is a modern technology infrastructure and data sharing platform that enables digital health information to flow seamlessly, privately, and securely wherever it needs to go. The Center for Medical Interoperability believes that this future state requires a new technology paradigm that connects all technologies across all healthcare settings with a secure platform. With this new trust platform, it will finally be possible to assemble a complete picture of a patient's health with data from medical devices, electronic health records, billing systems, and even mobile technologies.

C4MI envisions a world where health care data, including PGHD, is connected, digital, accessible, trusted, secure, and useful for doctors and patients alike. Accordingly, we are collaboratively designing and developing a vendor-neutral, non-proprietary industry platform approach that will establish the essential foundation of two-way digital trust between technologies.

The federal government has taken an active role in digitizing the American health care system through incentive payments and adjustments through programs like Promoting Interoperability. But the lack of interoperability in health care will not be solved through government action alone. It is incumbent upon the health care industry to demand and enable better care for our patients.

Data should be easily accessible by patients, be under their control, and be bidirectionally shareable with providers to inform better treatment. In order to achieve this, C4MI is developing a platform to allow the trusted and secure transmission of

patient data from all technologies, including CEHRT, medical devices, and other non-healthcare mobile technologies and applications.

While the HITECH Act catalyzed the move from paper to digital records via incentives and penalties for health care providers, it did not, unfortunately, address or create an underlying infrastructure of interoperability to enable data liquidity among technologies. In the case of EHRs, provider organizations are left to bridge the gap with a complex and costly mix of proprietary middleware solutions, technical one-off workarounds, and manual processes that contribute to clinician workload and fatigue. We have created a partially digitized system that still operates in proprietary data siloes and is more complex and burdensome than before. Most of this burden falls on the shoulders of provider organizations, but the impacts are felt by virtually everyone who provides or receives health care services.

The frustration with the current state of affairs has led the government to consider allowing third party applications and private market companies to solve the health industry's problems. The CMS and ONC proposed rules related to interoperability and patient access have the goal of enabling patients to access their health information electronically through third party applications connected to application programming interfaces (APIs).¹ However, providing unvetted third party applications open access to patients' digital health data is problematic from a consumer privacy standpoint and could serve to undermine the trust necessary in the provider-patient relationship.

C4MI believes there is a way to simultaneously protect the privacy of digital health care data while allowing the external marketplace of technology companies and innovators to interact with health care data in a responsible and productive way.

Need for a Trust Platform

Bidirectional trust is fundamental to health care – the patient must trust the provider and vice versa. When it comes to technologies, the recipient must trust the sender and vice versa. Without trust, these relationships cease to function properly.

To be able to operate and compete in the healthcare system of the future, the industry needs to establish an overarching software architecture that supports the free flow of information on a vendor-neutral, non-proprietary platform. C4MI is developing a trust platform architecture to support comprehensive interoperability, data liquidity, and trust among digital health data. This is a wide-ranging effort that seeks over time to align substantially all health-related digital information to a common platform architecture. Along with the technology specifications, the trust platform will be

¹ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 84 Fed. Reg. 7424 (proposed March 4, 2019); Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-Facilitated Exchanged and Health Care Providers, 84 Fed Reg 76103 (proposed March 4, 2019).

supported by the appropriate governance structure and data policies to maximize technical trust.

C4MI is working with its members, technology vendors, and others across the health care industry to design and develop the trust platform architecture. It will allow data from different technologies to flow from devices, record systems, clinical databases, data registries, and tailored applications safely and securely across the entire health care delivery system.

This platform approach is intended to be scalable from the individual episode of care to the operations of a large health system provider. At scale, this platform will unlock previously aspirational capabilities such as predictive analytics, artificial intelligence, and other models that rely on identified, contextualized, and computable data to improve care orchestration. A trust platform will be able to leverage operational tools such as the automated and secure update of medical devices to protect against cyberthreats. At the very least, connecting health care technologies through a trust platform will allow providers to focus on treating patients and practicing medicine rather than entering data, troubleshooting technology, and juggling segregated data points vital to proper treatment.

The trust platform approach leverages a platform model to provide size, scale, and trust characteristics to accelerate adoption. This is facilitated via an underlying technical architecture that provides uniform interfaces and data models for communication and an accompanying governance model to allow stakeholders to interoperate confidently with conformant systems. This approach enables fast adoption at massive scale and low cost. The trust platform is comprehensive across healthcare settings in that it encompasses trusted data interoperability and interactions at the point of care, between care settings, between locations and organizations, with the person, and with the external application marketplace.

C4MI will demonstrate the utility of the trust platform through specific clinical use cases and provide implementation specifications and guidance to scale the platform across health care systems. Acting in its role as a centralized lab, C4MI will test, verify, and certify products, tools, and solutions to help leverage the platform's architecture in new directions as determined by the health care marketplace.

C4MI is modeled on the belief that this platform must be driven by the purchasers and users of health technologies. Hospitals, health systems, and other large purchasers of health care technology and services, including the federal government, should align on the principles and technical requirements of the platform architecture, factoring those requirements into their individual procurement activities to operationalize the transformation. 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 and trusted platform for interoperability, it will allow them to simplify and decouple their proprietary products by leveraging the data from not only their products but from any

others as needed. Everyone will benefit from the innovations, efficiencies, and safety improvements that result.

C4MI and its members look forward to continuing to work with a broad set of stakeholders, including the federal government, to ensure there is alignment and a sustainable path to ensure such a trust platform is deployed and maintained at scale.

Responses to RFI

C4MI believes that PGHD should begin to enter the world of clinical care, but we also recognize that the clinical utility of such information has some limitations. For example, the technologies used by patients to record health data may not be as reliable as those used in a clinical care setting. Additionally, the circumstances surrounding a particular instance of patient data generation could render that data unreliable if, for example, data was entered incorrectly or recorded at a time or place that caused an inaccurate measurement. Ensuring that the data is trusted and valid is fundamental for its use to become standard clinical practice. C4MI believes that a trust platform, along with complementary specifications and certification testing for particular use cases, will help establish trusted modalities for use in clinical care that incorporate patient data generation.

In addition, the voluminous amount of data from PGHD may not be suitable for direct consumption into an EHR. Trusted data can be normalized and presented to care providers in a useful way, as illustrated by C4MI's work with data from patient monitors. A trust platform can provide tools and capabilities to facilitate a number of services, including data analytics and data presentation, to ensure that PGHD is useful for care providers making critical decisions.

Use Cases

As CMS considers what use cases may be most promising, C4MI encourages CMS to balance the potential benefits that incorporation of PGHD in CEHRT will bring with the burdens of providers and the potential for inaccurate information in the absence of a trust platform and certified methods for recording PHGD. Provider organizations and societies should be able to provide more specific recommendations on this topic, and C4MI encourages CMS to consider those comments.

As one potential area for consideration, diabetes management poses a particularly interesting value proposition. Data from continuous glucose monitors combined with behavioral data from an individual's fitness or diet tracker could help clinicians better manage an individual patient's diabetes and intervene before a more serious clinical intervention is necessary. However, the patient surveillance involved in such a scenario would need to be carefully considered by all parties with a focus on ensuring the patient is aware of how their data will be used and disclosed. Trust is key for both the data to be usable by the clinical team but also for the patient to willingly share the data at the outset. Other examples include heart disease, medication adherence, and many more.

Incentivizing Use of PGHD through the Promoting Interoperability Program

Incentive payments are always helpful in inducing behavior, but CMS should be cautious in choosing its course with the Promoting Interoperability program. Incentive payments can easily turn into mandates and penalties, and promoting the use of electronic health record systems is still mired by clinical burdens associated with the Meaningful Use program. Rather than incentivizing specific uses of data by clinicians, CMS should consider investing in making PGHD usable in the practice of medicine.

Current barriers to the use of PGHD could be solved with the widespread adoption of a trust platform that operates from the point of care to the patient interfacing portal or application and everything in between. C4MI believes that the private market is tasked with the responsibility for developing and scaling this trust platform, but the private market will need encouragement from the federal government to succeed. C4MI welcomes more in-depth discussion with CMS leadership and staff on how CMS and C4MI could work together to connect the disparate technologies used in the delivery of health care.

Collecting Data Outside of Routine Patient Visits

C4MI envisions a future where health care data flows seamlessly between care providers, patients, and others involved in the delivery of care. The seamless exchange of health information cannot be limited to in-person interactions between patients and clinicians. Instead, patients should be able to share updates to their health status through applications, wearables, messaging, and other means of data exchange, but all of this should occur through a means trusted by all parties involved. This is why C4MI is developing a trust platform to allow technologies to connect through a secure and trusted channel that will allow information to flow not just from a doctor to a patient, but also from the patient to the doctor and from the patient or doctor to any other trusted node connected to the platform and adhering to the specifications and requirements of data sharing policies and regulations.

Unfortunately, the current state of health care technology and infrastructure does not allow for this type of seamless data exchange, so C4MI cautions CMS against requiring providers to incorporate additional information into CEHRT before that information can be trusted and useful for both the care team and the patient. The duty of care to a patient is not limited to scheduled appointments or procedures, but CMS should be careful in requiring the incorporation of data that may not be trusted or useful in the delivery of care, especially considering the potential burdens that may follow.

Rewarding Providers for Optimizing Workflows to Obtain, Review, and Analyze PGHD

CMS should be cautious in rewarding or incentivizing providers to use or begin to use PGHD. While the federal government certainly should encourage the sharing of health

data, incentives and rewards can easily turn into mandates and penalties. C4MI believes that CMS should encourage the access, exchange, and use of all health data, including PGHD, but that CMS should ensure that it is not burdening clinicians now or in the future. CMS should explore partnerships with providers to encourage the development and facilitation of seamless health care data exchange, including a foundational trust platform infrastructure. C4MI welcomes further conversation with CMS leadership and staff on how development and deployment of a trust platform at scale could revolutionize the practice of health care and the use of data to improve outcomes for patients and providers.

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.

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