

June 3, 2019

Attn: CMS-9115-P
The Honorable Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: *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 Exchanges and Health Care Providers (Docket No. CMS-9115-P)*

I. Introduction & Statement of Interest

The Connected Health Initiative (CHI) appreciates the opportunity to provide input to the Centers for Medicare & Medicaid Services (CMS) on its proposed rule to move the health care ecosystem in the direction of interoperability. This proposed rule will also improve access to, and the quality of, information that Americans need to make informed healthcare decisions. This includes creating access to data about healthcare prices and outcomes, while minimizing reporting burdens on affected plans, healthcare providers, or payers.¹

CHI represents a broad consensus of stakeholders across the healthcare and technology sectors. Our mission is to support the responsible and secure use of connected health innovations throughout the continuum of care to improve patients' and consumers' experience and health outcomes. We seek to partner with the Department of Health and Human Services (HHS) in realizing the benefits of an information and communications technology-enabled American healthcare system. In particular, CHI is committed to advancing an interoperable healthcare continuum that enables the bidirectional flow of necessary health data between provider and patient, as well as between other important stakeholders who have a role in improving care coordination and decision-making.

¹ 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 Exchanges and Health Care Providers, 84 FR 7610 (Mar. 4, 2019) ("Proposed Rule").

II. General Comments of the CHI

CMS' proposed interoperability rules come at an important time. There is no disputing that interoperability and patient access to health information are preventing timely and informed care coordination and decision-making. Further, electronic health information and educational resources are critical tools that empower and engage patients in their own care. CHI strongly believes that a truly interoperable eCare system includes patient engagement facilitated by store-and-forward technologies (ranging from medical device remote monitoring products to general wellness products) with open application programming interfaces (APIs) that allow the upload of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized formats with interoperability facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms for data streams from multiple and diverse sources will improve the healthcare sector, helping to eliminate information silos, data blocking, and deficient patient engagement. Interoperability must not only happen between providers, but also between remote patient monitoring (RPM) products, medical devices, and EHRs. CMS and other federal actors must leverage voluntary industry standards along with consensus on standards (and testing to such standards) for interoperability between EHR systems, medical devices, and other healthcare products.

CHI is generally supportive of CMS' efforts to facilitate interoperability and facilitating greater data access throughout the care continuum. CHI generally urges for a logical, objective approach to reduce confusion, and urges CMS to align its rules with the certified capabilities of health IT vendors—i.e., the U.S. Core Data for Interoperability (USCDI) and APIs—with interoperability being evaluated through the lens of access, use, and exchange of the USCDI. And while CHI supports reliance on the USCDI, we call on HHS to acknowledge the limitations of USCDI Version 1.0. This version does not fully support the necessary elements for payer to member, payer to payer, and payer to provider information exchanges. CHI urges CMS to work with ONC to prioritize its effort to establish and follow a predictable, transparent, and collaborative process to expand the USCDI, including providing stakeholders with the opportunity to comment on the USCDI's expansion.

CHI agrees with the use of the Fast Healthcare Interoperable Resources (FHIR) standard and supports requiring the adoption of FHIR Release 4 and compliance with HL7 U.S. Core FHIR Implementation Guides. We believe that it will be much more conducive to realizing an interoperable healthcare ecosystem if one version of FHIR is used.

CHI appreciates CMS' discussion of "unscrupulous actors" that use apps to profit from an individual's information in ways that the individual did not authorize or understand.² CHI members include leading digital health app developers who build transparency and privacy concepts into their innovations "by design" as a matter of principle and ethics. Our members condemn the unethical sharing of sensitive health information with third parties, particularly when it is done without the knowledge of an individual. If beneficiaries access their and their family's health data—some of which are likely sensitive—through a smartphone, patients should have a clear understanding of the potential uses of that data by developers. Otherwise, most patients will not be aware of who has access to their medical information, how and why they received it, and how it is being used. The downstream consequences of using data in this way may ultimately erode a patient's privacy and willingness to disclose information to his or her healthcare provider. CHI is in agreement that it is in the best interest of the consumer/user to understand how their data is being used. Like ONC, CMS should establish an aligned framework outlining high-level data privacy and security guardrails that addresses individual access; data collection, uses and disclosures; consent and authorization; breach mitigation procedures and consumer notice; and security practices. Such a framework could be implemented to support Blue Button 2.0, serve as a model for health plans impacted by this Proposed Rule, and could potentially align with HIPAA or the certification requirements for trusted health information exchanges. Finally, CHI notes that if a company is selling and/or sharing user data, that company should clearly explain why and how that data is being shared (in plain language, as opposed to unnecessarily long and complicated end user license agreements), and how it will be used so that the consumer can make an informed decision and provide affirmative consent mechanisms for certain uses.

CHI notes its general support for making data available to patients needed to promote transparency and fair market competition. Such information's availability will advance Congress' goals for transparency, benefitting patients and consumers. However, we urge CMS to focus on providing patients with information that is useful to patients consistent with Congress' intent. Large data dumps on patients for the sake of releasing data may only serve to confuse patients.

It is also crucial for CMS to ensure that its interoperability rule aligns as much as possible with the information blocking rules in development by the HHS Office of the National Coordinator for Health IT (ONC). Should the rules diverge, stakeholders may be put into a position where they are forced to violate one rule in favor of the other (e.g., meet the requirements of the CMS interoperability rule but face ambiguities as to whether the requirements of an exception to ONC information blocking is being satisfied). CHI acknowledges CMS' (and ONC's) efforts to coordinate and supports those efforts. CHI is deeply engaged in this parallel rulemaking on information blocking and is appending its comments to ONC to this comment on the proposed CMS interoperability rules.

² *Id.* at 7622.

Finally, we urge CMS to provide impacted stakeholders with adequate time to technical and operations capabilities needed to address compliance with new information blocking rules. To provide this needed time, CHI urges for a delay of the rule's implementation until 2021, and to not be earlier than the implementation deadlines in the ONC Rule, which instantiate the prerequisite data standards including FHIR and USCDI.

III. Specific Comments of CHI

Based on the interests of CHI and our general views above, we provide the following specific input on CMS' proposed rule:

- **Technical Standards Related to Interoperability**
 - ***§422.119 Access to and exchange of health data and plan information:*** CMS requests comments on “the proposed alignment of standards in this proposed rule to those proposed for adoption by HHS through ONC’s 21st Century Cures Act proposed rule, as well as on the best method to provide support in identifying and implementing the applicable content and vocabulary standards for a given data element.”³
 - CHI supports the alignment of CMS’ interoperability rule with the ONC information blocking rule generally, and we encourage both agencies to align their rules’ terminology and requirements. While both CMS and ONC have admirable goals that CHI shares, we believe it could discourage interoperability should one rule adopt standards that are out of sync with the other.
 - CHI also urges CMS to continue to work with stakeholders and other federal agencies to focus interoperability efforts on promoting data consistency and access. This must include balancing policy goals with a sensible timeline. CMS should align future reporting programs around clinically led efforts that aim to advance terminologies, data elements, coding, and common data models to promote interoperability.
 - ***§422.119 Access to and exchange of health data and plan information:*** CMS proposes that “the applicable entity must comply with regulations regarding certain content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless an alternate standard is required by other applicable law. Specifically, we propose the applicable entity must use: Content and vocabulary standard ONC proposes for HHS adoption at 45 CFR 170.213 (USCDI Version 1) where such standards are the only available standards for the data type or element.”⁴
 - CHI supports this proposal, noting that changes will also need to be made to the USCDI itself to realize the goals of CMS.

³ *Id.* at 7623.

⁴ *Id.*

- **Patient Access Through APIs**

- **§422.119 Access to and exchange of health data and plan information:** CMS proposes to require “use of the following content and vocabulary standards for data available through the API, where applicable to the data type or data element, unless an alternate standard is required by other applicable law: standards adopted at 45 CFR part 162 and 42 CFR 423.160; and standards proposed by ONC for adoption by HHS at 45 CFR 170.213 (USCDI Version 1).”⁵
 - Noting our support for alignment of the CMS and ONC rules, CHI has recommended to ONC the adoption of FHIR version R4 in addition to the USCDI.
- **§422.119 Access to and exchange of health data and plan information:** CMS proposes that “MA organizations, Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers in FFEs, permit third-party applications to retrieve, with the approval of an enrollee, certain specific data: adjudicated claims data, including provider remittances and beneficiary or enrollee cost-sharing data; encounters from capitated providers; and clinical data, including laboratory results (but only if managed by the payer).”⁶
 - CHI supports making all data available to patients that may be useful to the patient but believes that CMS’ proposal contains an ambiguity regarding “encounters from capitated providers.” We note that the HL7 FHIR standard captures an encounter (the metadata of a clinic visit or hospital admission – date, time, location, service type, etc.)⁷ but that this data is not automatically included within that encounter. If the intent is to include all encounter-related data, these data elements (captured in USCDI) should be listed individually to remove any ambiguity. For example, the current draft rule contains focus on “laboratory results” and we do not understand why this element merits additional focus over other elements.
 - We note that claims information can be complex and erroneous, and patients have varying levels of health and technology literacy. Medicare populations often need assistance navigating the complexity of the system. As such, beneficiaries and the individuals assisting them should have assurances that information provided across settings (e.g., online web portals, smartphone apps, payer policy booklets) contain consistent information.

⁵ *Id.* at 7630.

⁶ *Id.* at 7632.

⁷ See more here: <https://build.fhir.org/ig/HL7/US-Core-R4/StructureDefinition-us-core-encounter.html>.

- **§422.119 Access to and exchange of health data and plan information:** CMS proposes that data should be made available “only if managed by the payer.”⁸
 - CHI finds this terminology not to be specific enough and urges for clarity as to what “managed” means in the context of this rule and this specific proposal. For example, CHI is unclear as to whether the term applies only to lab results, or to all clinical data. In addition, a payer may not manage data stored in a provider’s EHR, making it unfair to require such data from a payer. CHI suggests that CMS clarify that “managed by the payer” means “electronically stored in a database under the payer’s control.”
- **§422.119 Access to and exchange of health data and plan information:** CMS proposes to require “the encounter data to be available through the API within a certain period after the encounter, within one (1) business day after the encounter data is received” and whether that is a reasonable period from the encounter date to consider as part of future rulemaking.⁹
 - CHI believes that if data is received electronically and does not need to be reviewed or processed manually, the data should be made available as soon as practicable once received. We believe CMS should allow covered health plans seven business days to “refresh” information after the plan has received and verified the data; this timeframe is consistent with the Blue Button 2.0 refresh schedule where Medicare Parts A and B claims data is updated weekly.
- **§422.119 Access to and exchange of health data and plan information:** In discussing public accessibility, CMS states that it expects “any person using commonly available technology to browse the Internet could access the information without any preconditions or additional steps beyond downloading and using a third-party application to access data through the API.”¹⁰
 - CHI supports this proposal by CMS. However, we further propose that CMS align its language with relevant proposal text from ONC, which states that “documentation should be accessible to the public via a hyperlink without additional access requirements, including, without limitation, any form of registration, account creation, “click-

⁸ Proposed Rule at 7632.

⁹ *Id.* at 7633.

¹⁰ *Id.* at 7634.

through” agreements, or requirement to provide contact details or other information prior to accessing the documentation.”¹¹

- **§422.119 Access to and exchange of health data and plan information:** CMS states that “a covered entity is not expected to tolerate unacceptable levels of risk to the PHI held by the covered entity in its systems, as determined by its own risk analysis. Accordingly, it may be appropriate for an organization to deny or terminate specific applications’ connection to its API under certain circumstances in which the application poses an unacceptable risk to the PHI on its systems or otherwise violates the terms of use of the API technology.”¹²
 - CHI believes that the scenario discussed by CMS could constitute information blocking under the ONC rules, even if it is unintentional. CHI therefore requests that CMS include a reference at this point in the rules to ONC’s information blocking definition and how unacceptable levels of risk could meet an exception to information blocking in the ONC proposed rule.¹³
- **API Access to Published Provider Directory Data**
 - **§422.119 Access to and exchange of health data and plan information:** CMS proposes to require “the API technology conform to the API standards proposed by ONC for HHS adoption at 45 CFR 170.215 (published elsewhere in this Federal Register).”¹⁴
 - CHI supports CMS’ proposal that Payers expose provider directory information through an API to current enrollees, prospective enrollees, and the general public. We advise CMS to make it a requirement for qualified health plans (QHPs) in federally-facilitated exchanges (FFE), as well. We also urge CMS to require Payers to update their provider directories in real-time and to expeditiously correct errors.
 - CHI notes that 45 CFR 170.215 does not specify a standard for the provider directory data. Consistent with our views expressed to ONC, we urge for the use of the Argonaut Project, which has created an implementation guide for provider directories.¹⁵

¹¹ See 45 CFR 170.315(g)(10)(vii).

¹² Proposed Rule at 7635.

¹³ 45 CFR 171.201.

¹⁴ Proposed Rule at 7639.

¹⁵ <http://www.fhir.org/guides/argonaut/pd/>.

- **Request for Information on Advancing Interoperability Across the Care Continuum**
 - CMS requests input on how “HHS can more broadly incentivize the adoption of interoperable health IT systems and use of interoperable data across settings such as long-term and PAC, behavioral health, and those settings serving individuals who are dually eligible for Medicare and Medicaid and/or receiving home and community-based services.”¹⁶
 - Electronic health information and educational resources are critical tools that empower patients to engage in their own care. A truly interoperable connected healthcare system includes patient engagement facilitated by asynchronous (also called “store-and-forward”) technologies (ranging from medical device remote monitoring products to general wellness products) with two-way open APIs that allow the integration of PGHD into EHRs. Data stored in standardized, interoperable formats facilitated by APIs provides analytics as well as near real-time alerting capabilities. The use of platforms to manage data streams from multiple and diverse sources will improve the healthcare sector, and help eliminate information silos, data blocking, and barriers to patient engagement. Interoperability must not only happen between providers and patients, but also between RPM products, medical devices, and EHRs. We further recommend that CMS considers adopting the same standards as outlined in 45 CFR 170.213 and 170.215 (FHIR, USCDI v1) at minimum. Once this basic infrastructure is in place, it could be expanded to include PAC-specific data elements such as functional status, pressure ulcers/injuries, and other important data elements.

¹⁶ Proposed Rule at 7654.

- **Establishing Principles for Promoting Interoperability in Innovative Model Tests**
 - CMS states that “[n]ew Innovation Center models may also require that providers and other health care entities with direct patient interactions provide patients access to their own electronic health information and, upon the patient’s authorization, to third party developers via APIs.”¹⁷
 - CHI supports CMMI’s vision for exploration of new and innovative test models consistent with its effort to take CMMI in a “New Direction.”¹⁸ Generally, we support the systematic consideration of how new models advance health data interoperability and greater use of PGHD, and urge that such considerations be incorporated into model evaluation. For example, we support that providers and other healthcare entities with direct patient interactions provide patients access to their own electronic health information and, upon the patient’s authorization, to third party developers via APIs, as part of its model requirements,. While there have been many efforts to make data available from health systems via open APIs, the same has not been done for other potential sources of data, such as pharmacies, standalone diagnostic centers, device manufacturers (e.g., continuous glucometers), or genomics vendors. We believe that all data generated about a patient should be made available to them via APIs. Patient access and interoperability across the care continuum must be a short- and long-term priority for CMMI.
 - While we strongly support patient access to health information, we urge CMS to also consider health care providers’ need for data to drive innovative care delivery. It has been difficult for providers to provide higher-value care and succeed under APMs because they do not have access to the data needed to do so. For example, physicians developing proposed APMs cannot project how much Medicare and other payers would save because they cannot access payer claims data. We recommend providing easy, affordable ways for physicians to access and analyze Medicare claims data—even before they apply to participate in an APM—and establishing effective Health Information Exchanges so that health care providers can identify opportunities to reduce spending, measure the impacts of care delivery changes, and quickly identify when services for patients need to be changed.

¹⁷ *Id.* at 7656.

¹⁸ See <https://innovation.cms.gov/initiatives/direction/>.

CHI appreciates the opportunity to submit its comments to CMS. We look forward to assisting CMS in realizing a technology-enabled care continuum that provides maximum value to patients at the lowest costs.

Sincerely,

A handwritten signature in black ink, appearing to read "Brian Scarpelli". The signature is fluid and cursive, with a prominent loop at the end.

Brian Scarpelli
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