Centers for Medicare & Medicaid Services
Center for Program Integrity (CPI)

Electronic Medical Documentation Interoperability (EMDI) Program

2019 CMS Interoperability Proposed Rule Public Comments and Relevance to EMDI

Glossary

ACRONYM	STANDS FOR
ADT	Admissions, Discharges and Transfers
API	Application Programming Interface
EHI	Electronic Health Information
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level Seven International
MA	Medicare Advantage
QHP	Qualified Health Plan

ONC Proposed Rule vs. CMS Proposed Rule

ONC Proposed Rule for Interoperability of Health IT

- Updates the existing **2015 Edition certification criteria** regarding the exchange of electronic health information (EHI)
- Implements **information blocking provisions** of the 21st Century Cures Act
- Includes a **request for information** regarding EHI and pricing
- Is a **cross-agency and interdepartmental** effort

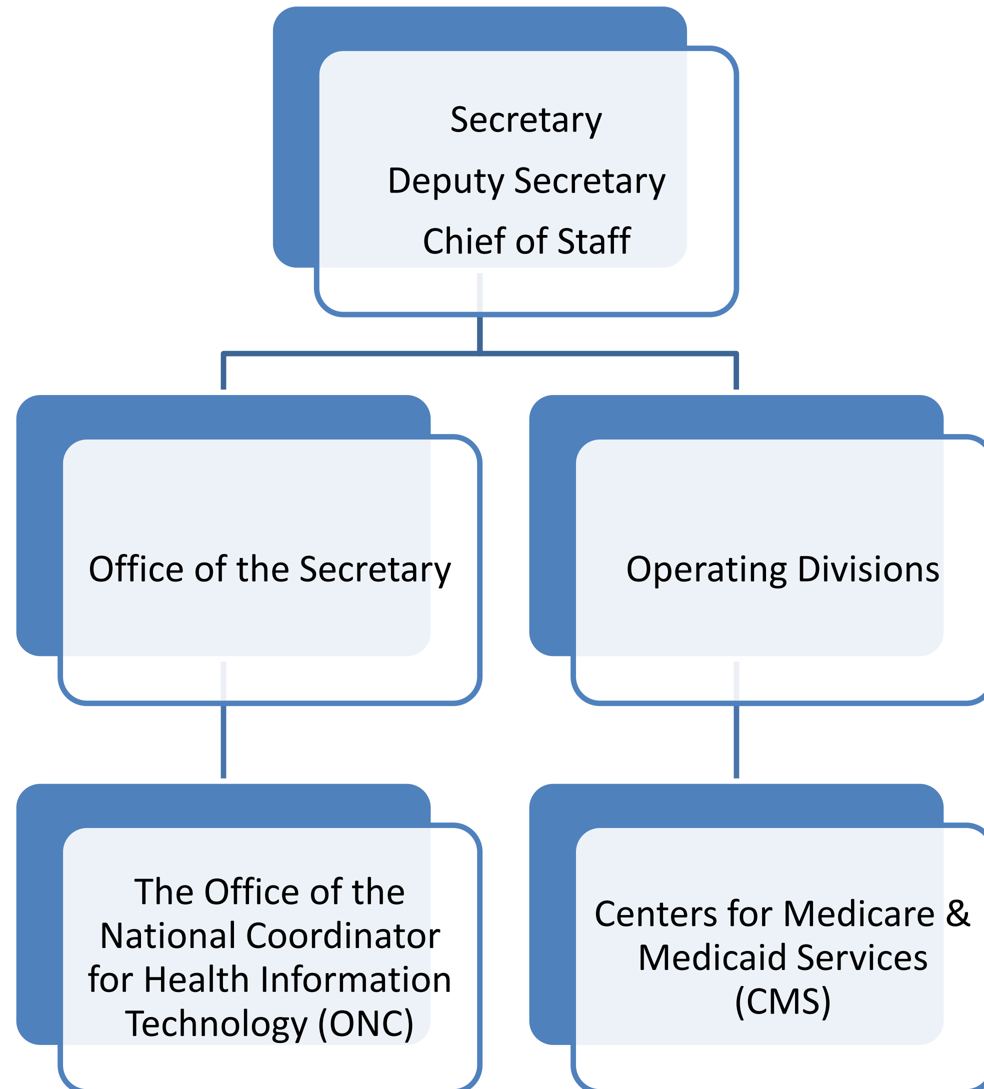
CMS Proposed Rule for Patient Access to Health Information

- Proposes **claims and encounter data** follow the person
- Requires **electronic notifications** for admissions, discharges and transfers (ADTs)
- Requires availability of **Provider Directories** via open APIs (FHIR)
- **Reaches ALL entities** that CMS regulates
- Includes **requests for information** regarding patient matching and health IT adoption in post-acute care
- **Defers to or references ONC proposed rule**

Why Two Separate Rulemakings?

- ONC's proposed rule is driven by requirements outlined in the 21st Century Cures Act of 2015 (Cures Act); broader reach than the CMS proposed rule
- CMS' proposed rule is driven by the White House MyHealthEData Initiative and the CMS Patients Over Paperwork Initiative
  - Designed to help patients easily access their complete health information in interoperable forms across the many programs CMS administers
  - Applies to health care providers, stated Medicaid and CHIP agencies, insurers that offer qualified health plans (QHPs), Medicare Advantage plans, or Medicaid managed care plans

HHS Organizational Chart



- **Advises the President**
- Oversees the Food and Drug Administration
- Set Medicare and Medicaid policies
- Manages the CDC
- Oversees Native American Health Services

- Includes eight agencies in U.S. Public Health Service and three human services agencies
- Administers a wide variety of health and human services
- Conducts national research

- Supports widespread adoption of Health IT
- Promotes nationwide health information exchange to improve health care

- Oversees federal health care and Health IT programs
- Administers health care reimbursement programs
- **Functions as a regulatory entity**

CMS Proposed Rule
Public Comments and Relevance

Public Comments

- 1,623 public comments submitted regarding CMS Interoperability and Patient Access proposed rule
- 152 comments relevant to health IT interoperability addressed the following topic categories (see next slides)

Public Comment Categories

- Advancing interoperability across the care continuum
- APIs
- Care coordination
- Data exchange and data transfer
- Direct-to-consumer applications
- Dual eligibles
- Information blocking
- Patient event notifications

Public Comment Categories, cont'd…

- Patient matching
- Post acute care providers
- Privacy and security
- Proposed timeframe for adoption
- Provider directory
- Public disclosure of information blocking
- Trusted exchanges

Public Comment Categories Relevant to EMDI

- Advancing interoperability across the care continuum
- API technical standards
- APIs between providers and payers
- Care coordination
- Data exchange
- Patient event notifications
- Post-acute care providers
- Trusted exchanges

Advancing Interoperability Across the Care Continuum

Comment	Submitter and Relevance
The greatest transition of care risk is from the acute hospital setting to any other setting. Some post-acute providers have EHRs that can receive data, but it is often difficult for 9 Proposed Rule, pages 7678 and 7679. 10 Proposed Rule, pages 7654. 6 hospitals to share the data with these providers. APTA agrees that CMS should put forth a policy to incentivize this data transaction, and it should be at no cost to PAC providers. APTA also encourages CMS to address the health IT adoption and interoperability needs of physical therapist private practices. Physical therapists may need additional time to obtain EHR systems and the technical and financial capacity to collect and share electronic health care data. We urge the agency to consider financial incentives to alleviate the costs that physical therapists and other providers that have been excluded from Meaningful Use will no doubt face in complying with new interoperability requirements. Moreover, any interoperability requirements on PAC providers should allay concerns that such providers, as well as nonphysician providers and suppliers, including physical therapist private practices, are treated unfairly. For instance, a physical therapy practice could be pressured by a hospital to become interoperable if the practice wants access to the data. However, the fees and resources needed to become interoperable likely will be too high for the private practice to overcome. In turn, the practice could be faulted unfairly for information blocking. APTA also recommends that CMS afford small and rural practitioners and practices an exception to interoperability requirements. Providers and practices in rural areas often experience difficulties in acquiring the necessary technology to support EHR systems at a reasonable cost. **However, APTA recommends that CMS offer financial incentives to these small and rural practitioners and practices that can feasibly become interoperable but would suffer a financial hardship as a result of any future interoperability standards. We recognize that CMS's goal is to encourage as many providers as possible to improve interoperability across care settings, but we do not support burdening these providers with financial hardships to achieve greater interoperability.**	Submitted by American Physical Therapy Association (physician) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
As noted above, we have observed significant strides in both the LTPAC and behavioral health communities, particularly the former. Much of this momentum is relatively recent. By no means do we suggest that all challenges will solve themselves in the short term without CMS assistance or action; rather, we believe the recent progress by early adopters likely makes the timing right for **action by CMS that focuses on incentives to adopt interoperable technology and participate in trusted exchange networks in the short to medium term.**	Submitted by The Sequoia Project (advocacy organization) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
As part of this proposed rule, the CMS Innovation Center (CMMI) seeks public comment on the principles for promoting interoperability as it considers interoperability requirements for all CMMI models going forward. AMRPA recognizes that CMMI models represent an important potential opportunity to advance progress toward interoperability. However, AMRPA does not support CMMI using innovation models as a "lever" for advancing interoperability, as CMS states in the rule. **There is a high degree of variability in EHR adoption across care settings due to the lack of incentive funding for all care settings. AMRPA is concerned that any move to make interoperability a prerequisite for CMMI model participation would only further exacerbate the existing disparities in EHR adoption and disadvantage those providers and settings (PAC, behavioral health, and community-based services, rural providers) that are already at a disadvantage vis-à-vis achieving interoperability. CMS should strive to use CMMI funding as a means of supporting and enabling interoperability across the health care continuum and not use interoperability as a barrier of access to innovation funding.**	Submitted by American Medical Rehabilitation Providers Association (long-term care provider) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
Certainly, LTPAC providers, and their patients, will benefit from widespread adoption of interoperable HIT. **However, AAPACN asserts that CMS should not penalize the way to widespread adoption of HIT systems in LT PAC settings. Instead, CMS should offer 3 financial incentives through a program modeled upon Meaningful Use, offering a timeline, implementation goals and incentives for progress made toward implementation goals. Alternatively, CMS should offer payment adjustments through the respective Prospective Payment Systems for various PAC settings for achievement of bidirectional, interoperable health IT systems.** These payment adjustments should be based on a multiple of actual costs incurred for system acquisition, implementation and training costs, including staff wages. Finally, AAPACN urges CMS to adopt a financial reimbursement program to compensate early adopters of interoperable HIT systems. Further, timelines for implementation must consider sufficient and necessary time for health IT vendors to draft, implement, test and deploy software, as well as the time for providers to implement and train staff on new software. Finally, **CMS should establish timelines to increase adoption of interoperable health IT across LTPAC settings that recognize both the existing provider burden from current CMS mandates as well as the lengthy timeframes other providers been afforded for health IT implementation**. Current mandates impacting LTPAC providers include, but are not limited to, the Improving Medicare Post-Acute Care Transformation" Act of 2014 (IMPACT Act) and new prospective payment system in two PAC settings in 2019. Further, hospitals and physician practices have had over nine years to implement HIT under the Meaningful Use program. LTPAC providers should be afforded an appropriate timeframe of several years to complete adoption.	Submitted by American Association of Post-Acute Care Nursing (association) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
AARP appreciates CMS seeking feedback about advancing interoperability across the care continuum**. A person- and family-centered care system demands interoperability given the care transitions that many Medicare and Medicaid beneficiaries experience. Exchange of information across acute, post-acute, long-term services and supports (including home and community-based services), and behavioral health providers, and other settings serving dually eligible individuals is vital. As CMS notes, many non-acute care providers have not adopted health information technology at the same rate as acute care hospitals, and they have not had the support that other providers have had to do so.** CMS invites comment on policy strategies HHS could adopt to deliver financial support for technology adoption and use in these settings. AARP urges CMS, and if needed Congress, to adopt or support incentives similar to those provided to acute care providers to support the adoption of health IT in other provider types and settings. CMS is also seeking comments on whether hospitals and physicians who have adopted certified electronic health record technology (CEHRT) should adopt the capability to collect and electronically exchange the same PAC standardized patient assessment data elements (e.g. functional status, pressure ulcers, etc.) that are required of providers under the Improving Medicare Post-Acute Care Transformation (IMPACT) Act or only a subset of these items**. AARP suggests that they should be required to collect the same data elements, and not just a subset of the PAC standardized patient assessment data elements**. This would help assure comparability of data across providers, rather than creating potential gaps and/or inconsistencies in the data. The sooner this could be implemented the better. In terms of advancing interoperability among innovative payment models under the Center for Medicare & Medicaid Innovation (CMMI), CMMI could require participants to begin collection of PAC data elements as soon as possible. This would provide opportunities to get started sooner with this process and begin to measure which approaches are most efficient and least burdensome.	Submitted by AARP (association) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
It is helpful to clarify definitions of PAC, behavioral health, and home/community settings. These settings are quite different, with PAC being predominantly comprised of health care providers, where use of an electronic health record is important. The other settings blend heavily into services that aim to address social determinants of health. Behavioral health providers include a blend of health care and non-health care services, with many home/community agencies heavily focused on non-health care support activities such as housing support, transportation assistance, and food security. **For those non-health care settings, an electronic health record is not essential to their core activities, but would rather enhance the ability to have interoperability for coordination purposes. In those cases, these settings would require significant (perhaps 100 percent) subsidy to justify the adoption and use of an electronic health record. We believe that it may be more useful to provide opportunities for interoperability between important non-health care settings primary software and a health information exchange (HIE) for basic information around patient demographics, key diagnoses, and care coordination.**	Submitted by Spectrum Health (health system) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
To inform its future rulemaking, CMS seeks input on strategies for advancing interoperability across care settings, including the inpatient psychiatric facility and post-acute care settings. Prior to adopting a regulatory framework to further promote interoperability for care coordination, CMS should conduct an environmental scan of current information sharing capabilities and activities of providers across all settings, assess what is working, and what needs to be further explored and tested. As GNYHA has commented in the past, a significant reason providers cannot achieve care coordination through interoperability is because much of the health care landscape still lacks electronic health records (EHR) and connectivity.	Submitted by Greater New York Hospital Association (health system) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
As CMS recognizes, PAC providers have not had the access to federal funding to adopt HIT that other providers have had. AMRPA appreciates CMS' recognition of this disparity and its request for feedback on ways to incentivize HIT adoption. AMRPA recommends that CMS (and if needed, Congress) adopt or provide incentives to support EHR adoption in PAC and other settings excluded from Meaningful Use. As a potential approach, CMS should consider a bonus payment framework that rewards PAC providers for achieving EHR adoption and demonstrating interoperable information exchange. This policy would not exclude PAC providers who have already dedicated considerable financial resources to integrating and adopting EHRs in their institutions. **Critically, any policy or initiative CMS implements to incentivize adoption must not come at a cost to PAC providers.** In other words, any incentive dollars made available to PAC must not be achieved through a "budget neutral" mechanism that depletes PAC funding from elsewhere in the Medicare program. Needless to say, it would further put PAC providers at an unfair disadvantage if PAC-specific EHR incentive payments were funded by reducing PAC funding elsewhere when no such budget neutral mechanisms were applied to acute-care providers that received funds under the Meaningful Use incentive program. The Meaningful Use program has been in place for nearly a decade and, despite progress, interoperability among acute care and ambulatory settings is still not reality. **Accordingly, AMRPA recommends PAC providers be afforded an adequate ramp-up period or "glidepath" before they can be held to the same interoperability standards as acute care or ambulatory settings.**	Submitted by American Medical Rehabilitation Providers Association (long-term care provider) **Provider-to-provider interoperability for post-acute care providers**

Advancing Interoperability Across the Care Continuum, cont'd…

Comment	Submitter and Relevance
Outpatient & Imaging Claims Data. **Although many hospitals and other providers share patient notifications based on admission, discharge and transfer HL7 feeds (ADT Feeds), for a number of technical and practical reasons, in many cases outpatient providers are not able to provide ADT Feeds. As a result, even in geographies where providers freely share ADT Feeds on hospital encounters for patients, it can be difficult for providers to get similar visibility into outpatient encounters. We believe that enabling providers to access outpatient claims encounter data from payers can be a very useful tool, despite the long lag time in availability of this data, in a broad range of use cases.** For example, outpatient encounter data could help an ED provider identify a patient's primary care provider or any specialists that a patient has seen. This could enable all providers to have a more complete and accurate picture of the clinical history the patient has experienced with outpatient providers by quick access to diagnosis and procedure codes. Importantly, enabling providers to have access to claims for imaging procedures can provide an extremely valuable tool to avoid unnecessarily repeating imaging studies—simply knowing an DocuSign Envelope ID: 3EE3413D-25E5-4AD6-A2DB-73E5A9ED5E51 4 imaging study occurred at a particular place and time could enable an ED provider to contact the other provider to obtain useful information and avoid an unnecessary imaging study.	Submitted by Collective Medical (health IT developer) **Provider-to-provider interoperability for post-acute care providers**

API Technical Standards

Comment	Submitter and Relevance
The FHIR-based API should be the only method for individual beneficiary data exchange, and FHIR standards should be further vetted for provider-plan and plan-plan exchanges. Note that the primary FHIR implementations to date have focused on the domains of electronic health record (EHR) systems, where support for personal health records has aligned closely with Meaningful Use certification. Much of this data remains locked in EHR systems and are not readily (or even currently) accessible by health plans. Specific health plans that are highly integrated with provider groups, or indeed have common ownership, are better positioned to have access to more granular health information. We believe, however, that the intent of these policies is to further free the availability of individual consumer health information for all Medicare beneficiaries, not just those who receive care within highly integrated health care delivery systems. **There is nonetheless benefit in promoting implementation of specific FHIR-based APIs, and having CMS require, or incentivize, MA plans to pilot or implement at least a certain number of proposed new specifications in order to spur the rapid testing and improvement of standards.** Rapid iteration is necessary to generate solid implementations for widespread industry adoption and value generation for beneficiaries. The release of FHIR v4 specifications will better support these serial improvements by enabling backwards compatibility, and **we therefore strongly encourage the sole adoption of FHIR v4 (per the ONC** NPRM).	Submitted by Clover Health (health IT developer) **Provider-to-provider interoperability** **Provider-to-payer interoperability** **FHIR APIs**

API Technical Standards, cont'd…

Comment	Submitter and Relevance
CMS and ONC should align the technical standards of their respective Proposed Rules. As noted above, CMS should incorporate (that is, adopt) ONC's standards for interoperability, health information access and data exchange by reference, rather than naming its own standards in regulation. This will ensure consistent standards for interoperability and information exchange across all programs and services. CMS' Proposed Rule would require development of new standards for each of the four proposed information exchange transactions: 1) health plan-to-member access to data about claims, encounters, financial responsibility, clinical records, and pharmacy benefits; 2) health plan-tohealth plan exchange of data about former enrollees; 3) provider directory data; and 4) formulary/pharmacy benefit data. The Proposed Rule outlines these transactions only in broad terms. **We recommend CMS support ONC in adopting HL7 Fast Healthcare Interoperability Resources Release 4 (FHIR R4) standards and the USCDI to define the data content, structure, and format of each exchange done via a standard API.** It is important for CMS and ONC to adopt only accredited American National Standards, or consensus consortia standards meeting all conditions of the World Trade Organization Agreement on Technical Barriers to Trade (WTO TBT) or the ANSI Essential Requirements.8 Implementation guidance for these standards should be made available in subregulatory publications so that they may be updated more rapidly and more flexibly than can be managed though the regulatory rulemaking process.	Submitted by Kaiser Permanente (health system) **FHIR APIs**

API Technical Standards, cont'd…

Comment	Submitter and Relevance
We support adopting ONC EHI content and vocabulary standards and the application programming interface (API) technical standards. These standards enjoy broad international support, will help make EHI readily available and are moving in the right direction. **However, the Fast Healthcare Interoperability Resources (FHIR) and US Core Data for Interoperability (USCDI) are works in progress and will need substantial improvement to fulfill their promise**. For example, these standards do not yet include fields for data on social determinants of health, risk adjustment and stratification, care plan goal progress, care coordination, care transitions and opioid use. In addition, not all systems are ready to use these standards. We appreciate that there is a need to balance progress toward comprehensiveness with the ability of different stakeholders to adapt to these standards. We therefore urge you to incorporate any and all updates as quickly as feasible, if your final rule adopts these broadly supported standards.	Submitted by National Committee for Quality Assurance (health care accreditation organization) **FHIR APIs**

API Technical Standards, cont'd…

Comment	Submitter and Relevance
The Cures Act requires APIs that do not require special effort to exchange EHI. However, we are concerned that ONC is proposing the implementation of non-normalized exchange standards; specifically, the Fast Healthcare Interoperability Resources (FHIR) standards in their proposed rule. There are a number of health IT developers that will already be rushed by the short implementation timeline proposed in this rule. **We believe that it is directionally correct to guide the EHR marketplace toward FHIR, however, CMS should use FHIR R.4 to better ensure interoperability.**	Submitted by Health Information Alliance (association) **FHIR APIs**

API Technical Standards, cont'd…

Comment	Submitter and Relevance
We would specifically like to comment on the Request for Information on the sharing of information among providers and payers on a shared patient population and the use of application program interfaces (APIs) in the sharing of such information. We strongly support efforts to increase the sharing of patient information among providers that share the same patient. As IDTFs, we provide the technical component of diagnostic tests and transmit test data and analyses to the ordering practitioner. However, we have no access to any medical information maintained by the ordering physician. When IDTFs are audited by Medicare or when claims are denied based on medical necessity, or for not meeting any "step therapy" requirements imposed by the MAC, IDTFs must submit The Honorable Seema Verma Page 2 May 9, 2019 {D0832039.DOCX / 2 } medical records of the ordering physician to justify coverage. This often places an enormous regulatory and financial burden on IDTFs. Physicians have no obligation to turn over patient records to the IDTF even though they share the same patient. Nevertheless, without such documentation there is little the IDTF can do to challenge an audit or coverage denial. Further, although it is the ordering physician that makes the decision that the patient needs a particular test, it is the IDTF that is denied payment or is subject to recoupment when that decision is challenged. For these reasons, we support CMS' efforts to facilitate information sharing among providers. Electronic sharing of information through an API or other means would reduce administrative burden to both IDTFs and physicians and would facilitate appropriate payment.	Submitted by Health Information Alliance (association) **Provider-to-provider interoperability** **Provider-to-payer interoperability**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
The AAN supports CMS's efforts to advance the use of standardized, Fast Healthcare Interoperability Resources (FHIR) based APIs for patients to gain access to their health information. Patient access through open APIs to data including claims data, laboratory results, medications, and clinical notes is critically important to care coordination and to improving a patient's overall understanding of their health and course of treatment. Although the AAN supports improved access to this data, the AAN requests further clarification on how data that predates this rulemaking will be treated. Will patient data from legacy systems be required to meet the updated FHIR standard? The AAN is concerned that a requirement to update legacy EHI data to the new standard may be significantly burdensome on providers and practices. The AAN supports a requirement for vendors to implement these new standards, including potential legacy EHI, in a manner that should not place additional burden on provider and end-user configuration. The proposed rule requests comment on the "utility to providers of obtaining all of their patients' utilization history in a timely and comprehensive fashion."1 The AAN supports this and believes that it is of paramount importance that comprehensive patient information is available when it is needed. **The proposed rule also requests comment on the "potential unintended consequences that could result from allowing a provider to access or download information about a shared patient population from payers through an open API."2 The AAN applauds the transparency intent of this request and agrees that this information should be available for import into a provider's EHR. However, we caution that this should limit a providers' liability, in that clinical decision support tools used for population management, may vary by the end user. This information should be intended for educational purposes and not intended for direct patient care interventions until safeguards are in place** on how providers can reasonably interpret and accommodate this information into their clinical decision making.	Submitted by American Academy of Neurology (physician) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
The Academy agrees with the importance of fostering an integrated environment wherein clinical and administrative data sharing between payers and providers is seamless and fully functional. The scope of this request for information points to the critical need to test all these assumptions and validate technical aspects through a well-designed data exchange pilot that includes patients, providers and payers to determine relevant elements and processes as well as identify and remedy potential flaws between and among trading parties. The long-delayed HIPAA electronic attachment standards might be a useful starting point for a recommended pilot given its querying, response and acknowledgement elements and applicability to managing claims, prior authorizations referrals and other administrative data processes.	Submitted by American Academy of Dermatology (physician) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
We agree that the use of FHIR-based interoperability specifications should and will allow HIPAA covered entities that share beneficiaries to leverage open APIs to permit individual patient access to health information. Payer-provider APIs for bulk, or population-level, data-sharing should not be open and should be used as part of Business Associate Agreement (BAA) covered arrangements. As a PPO health plan with limited provider exclusivity, we 3 support the widespread use and access of the individual consumer-focused mechanism; this better enables care coordination in the common instances where patients receive care outside of a contracted network, especially in cases of emergency care. We believe that health plans would define shared payer-provider populations in their delegated provider contracts, where there are clear incentives to identify shared members. A similar compact between CMS and MA plans should be in place to support data sharing for care coordination purposes. In keeping with the intent to promote broader use of bulk data exchanges, we urge CMS to adopt the practice of sharing FFS data not only with ACO entities, but also MA plans, specifically at the point of new member enrollment with an MA plan. Doing so would facilitate care continuity and coordination by MA plans and enable plans to further share all acquired health information with consumers. **(CONTINUES ON NEXT SLIDE)**	Submitted by Clover Health (health IT developer) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
Similarly, in order to promote the use of v1 USCDI data set elements, we urge CMS to use USCDI specifications in their data files shared with MA plans. We would also note that the proposed USCDI minimum data set includes elements that are not commonly collected by MA plans (e.g., Patient Goals, Health Concerns, Medication Allergies, Unique Identifiers for a Patient's Implantable Device) and therefore should not be required data elements. If CMS seeks to require/permit further data aggregation across a range of USCDI element sources, there should be some mechanism to hold a plan harmless for transmitting data that may be mismatched, or to assure that consumers are able to review their data. Consider, for example, the common situation in which an incorrect or misinterpreted diagnostic code (from a rule-out diagnosis, for example) has been associated with a patient's record; the patient definitively does not have the diagnosis and may be upset to see it associated with her record. A plan would not be able to expunge that information from data that it received from a past paid claim to assure accurate interpretation and communication of that member's health information moving forward. **We recommend that further work on common error reconciliation processes and exchange policies be developed prior to requiring transmission of the full version 1 of the USCDI data set.** The proposed ONC rulings that would require standardized and codified provenance information, so that the original source of data is clearly and consistently identified (source, author, timestamp) would be helpful in this regard.	Submitted by Clover Health (health IT developer) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
We recommend that CMS provide a capability and versioning roadmap for API development, syntax and semantics that is regularly updated and rule adherence to that roadmap. This ensures a consistent experience for all constituents as well as stability to the SoS. We also recommend that the form of the API be explicitly ruled on: FHIR or JSON served by RESTful endpoints with explicit functionality. We recommend that CMS rule on providing capabilities like registering an application, providing a specific encounter for a patient, providing the last encounter for a patient, providing all encounters for a patient, and the same for a list of patients. This, too, will provide a better, more consistent experience for everyone.	Submitted by Centura Health (health system) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
The Sequoia Project agrees with CMS on the importance of standards and standards-based APIs to augment existing, proven interoperability standards and approaches. We also agree with its intent to incorporate by reference several standards and implementation specifications proposed in a companion proposed rule by the Office of the National Coordinator for Health IT (ONC).	Submitted by The Sequoia Project (advocacy organization) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
ONC is recommending Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) based APIs. **We suggest that CMS follow the same API recommendation as ONC, e.g. using the FHIR standard and Implementation Guides.** This may be CMS's intent, but statements referencing "openly published (or simply "open") APIs" are confusing since they imply any API is acceptable as long as it is published. This could result in thousands of proprietary APIs that will deter interoperability by requiring customized point to point APIs. Proprietary point to point APIs also seems contrary to The National Technology Transfer and Advancement Act (NTTAA) and OMB A-119 requirements for federal agencies. 2 Please clarify CMS statements referring to "open" APIs and "openly published" should be based on the FHIR based APIs recommended by ONC.	Submitted by Quest Diagnostics (clinical laboratory) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
etHIN, through its membership in SHIEC, the Strategic HIE Collaborative, has submitted comments to the ONC that we support the FHIR standard. This support assumes that HIEs and their providers may use FHIR 2.0 and progress to FHIR version 4 over time. We support sharing appropriate documentation to make connecting to these APIs accessible without special effort, but it is important to note that our community governance model reserves the right to ensure that those connecting to the data will not use it to the detriment of our HIE participants or their patients. Further, our community is in strong opposition to any requirement which would give access to data to individuals or organizations who will use that data to damage or destroy the HIE business model. While our community agrees that its mission and responsibility dictates that data should flow as freely as possible, there is a clear position of trust among participants and a clearly defined agreement on the uses of data. That model must be given due consideration and accommodated, or data sharing across many communities like ours could be jeopardized. Consideration of incentives to hospitals, clinics, and others to participate in a broader set of exchange activities through trusted exchange networks should be considered. etHIN generally supports patient access to Payer's adjudicated claims and would encourage that these claims are contributed to HIE/HIN's to ensure that longitudinal records provided by HIE/HIN entities to their participants are as complete as possible.	Submitted by East Tennessee Health Information Network (HIN) **Provider-to-payer interoperability** **FHIR APIs**

APIs Between Providers and Payers, cont'd…

Comment	Submitter and Relevance
In considering CMS's proposed timelines for adoption and deployment, AMIA recommends a phased approach for specific data proposed to be made available through open APIs. Specifically, we understand that HIPAA transaction standards, such as patient claims and encounter data, are more uniformly adopted across regulated industry. **And there is promising work underway to develop implementation guides for a set of resources that payers can display health data to consumers via a FHIR API.2 We anticipate that plans could more easily adopt these standards when compared to USCDI data and the NCPDP standards. While we support the inclusion of USCDI into these proposals, we note that the USCDI FHIR version and content/vocabulary have not yet been finalized by HHS.** While AMIA has recommended ONC finalize FHIR Release 4 and include the "unstructured document" template as part of the USCDI's Clinical Notes data class,3 formal implementation guides from HL7 will not be available for plans until later in 2019 (or possibly 2020). For this reason, **AMIA recommends CMS require the availability of USCDI data via "open API" as part of phase 2, likely not before 2021.**	Submitted by American Medical Informatics Association (association) **FHIR APIs**

Care Coordination

Comment	Submitter and Relevance
The AOA fully supports the CMS proposal to require CMS payers regulated under the proposed rule to maintain a process for the electronic exchange of the data classes and elements included in the U.S. Core Data for Interoperability (USCDI) Version 1 data set standard. By requiring data sharing between health plans, care coordination could be improved, and patients would have a more comprehensive account of the health care they have received.	Submitted by American Optometric Association (association) **Provider-to-payer interoperability**

Care Coordination, cont'd…

Comment	Submitter and Relevance
Finally, we recommend that CMS provide greater clarity around what it means to "incorporate" the data set into the recipient plan's systems under the proposed rule. **We agree with CMS that the provision of the USCDI will provide patients with a more comprehensive history of their medical care to assist them in making better informed healthcare decisions. However, as noted in our comments to ONC on its 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program proposed rule, we are concerned that the USCDI does not correlate to content exchange standards and implementation specifications and that the lack of such standards and implementation specifications will compound existing difficulties in exchanging electronic health information.** Expertise in data quality, integrity, and data stewardship positions HIM professionals well to address the incorporation of this data set and error reconciliation. However, additional clarification is needed from CMS as to its intention in requiring plans to incorporate the USCDI into a recipient plan's systems.	Submitted by American Medical Informatics Association (association) **Provider-to-payer interoperability**

Care Coordination, cont'd…

Comment	Submitter and Relevance
etHIN supports the exchange of data in the USCDI minimum data set and is happy to help our clinical partners facilitate this exchange. We support the requirement of CMS managed programs to participate 3 in trusted exchange networks, and as Trust Brokers of our communities, are well positioned to facilitate this effort with our Payer partners. We support requirements for hospitals to share clinical data, and we have the capacity to facilitate this data reaching those organizations who are technically capable of receiving it and clinically able to use it under HIPAA. **In addition, we support the requirement that psychiatric hospitals send admit, discharge and transfer information to organizations that can facilitate health information exchange.** We also support the inclusion of diagnosis coding in the ADT messages CMS is suggesting be a requirement. The addition of chief complaint would be a strong addition we would recommend, since both of these pieces of information are critical for Payers, care coordinators, and providers to respond to an emergency room admission in a timely manner.	Submitted by East Tennessee Health Information Network (HIN) **Provider-to-provider interoperability** **Provider-to-payer interoperability**

Care Coordination, cont'd…

Comment	Submitter and Relevance
Kaiser Permanente agrees that health plans should be able to generate and receive health information about existing or former health plan enrollees and to exchange that information with other health plans as appropriate. **However, health plans may not routinely collect much of the detailed clinical information contained in the USCDI, such as clinical notes, clinical lab results, data provenance, unique device identifier(s), and vital signs**. We recommend that CMS clarify that health plan-to-health plan exchanges will be limited to data collected about beneficiaries in the normal course of business, with no additional requirement to collect more clinical data than is necessary to conduct business and provide service to beneficiaries.	Submitted by Kaiser Permanente (health system) **Provider-to-provider interoperability** **Provider-to-payer interoperability**

Care Coordination, cont'd…

Comment	Submitter and Relevance
As part of the Proposed Rule, CMS proposes payers regulated under this Proposed Rule be required to maintain a process for the electronic exchange of the data classes and elements included in the UCSDI Version 1 data set standard proposed in the ONC proposed rule (45 CFR 170.213). This information when received from another payer would be required to be incorporated into the receiving payer's records about the enrollee. At the request of a current enrollee, the payer must receive the data from any other health plan that has provided coverage to the enrollee within the preceding five (5) years; for up to five (5) years after disenrollment send data to any other plan that currently covers the enrollee; and for a period of up to five (5) years after disenrollment send data to a recipient designated by a current enrollee. This requirement would be effective starting January 1, 2020**. First, we do not believe CMS should require the use of the API for this exchange of data. Requiring use of the API adds an intermediate step which removes all of the HIPAA protections from the data while in the possession of a middle-man. Any existing problems with the exchange of data between payers could better be addressed by implementing trusted exchange networks.** Also, using the API will require an additional step of obtaining an authorization from the patient/enrollee. This adds a layer of complexity where it is not necessary and is likely to delay the exchange. **Further, while we agree with exchanging a standard data set, the USCDI VI V1 is provider focused and may not accurately reflect all of the pertinent information included in a claim or encounter or other standard data helpful to a payer.** We recommend that CMS work with stakeholders to identify the data payers deem most important to guide direction on the necessary data set for payer to payer transactions.	Submitted by Highmark Health (health system) **Provider-to-provider interoperability** **Provider-to-payer interoperability**

Data Exchange

Comment	Submitter and Relevance
The Companies support the concept of data exchange and communications between providers as it provides a platform for providers to receive and provide critical patient information. This information would provide a vast amount of information that would assist in the care delivery, improved patient safety, and potentially improved outcomes. With that, additional development of health information exchanges (HIE) must occur prior to implementation. The development of HIE varies significantly between states and communities and is in its infancy. Until such time that stable HIE exists in all states, the exchange of data will be difficult. We recommend that efforts related to HIE become the immediate emphasis in order proceed with the interoperability goals.	Submitted by Vibra Healthcare (long-term care provider) **Provider-to-provider interoperability**

Patient Event Notifications

Comment	Submitter and Relevance
The Companies understand the desire and need to share pertinent patient information for the coordination of patient care and services across the health care continuum. As our hospitals are post-acute providers, we are acutely aware how vital sufficient and appropriate information such as patient diagnoses, treatments, and medications can be to providing quality care and prevent adverse outcomes such as hospital readmissions. **Although desirable, we do not believe that at this time, the post-acute sector of health care can be prepared to participate in the Proposed Rule exchange of information in an electronic format.** As discussed in the Proposed Rule, post-acute providers of care were not able to participate in the Electronic Health Record (EHR) Incentive Programs and receive the funding available to acute care hospitals and critical access hospitals. The Vibra and Ernest systems could not bear the costs associated with implementation of all sites without an incentive program that would mimic that provided to eligible hospitals. **The costs associated with either the implementation of a system that meets "meaningful use" or the necessary update of current systems exceeds the fiscal budgets for the Companies' hospitals**. **We would ask that CMS reconsider the proposal regarding the electronic patient event notifications for post-acute providers** including the IMPACT Act quality measures, SPADE measures, and other data elements until such time that a plan for consistent implementation and reliable funding can be assessed and implemented without disruption of post-acute services. This might require a Technical Expert Panel (TEP) whose membership would include post-acute providers and representatives of the American Medical Rehabilitation Providers Association (AMRPA) and National Association of Long Term Hospitals (NALTH). **Any change to the Conditions of Participation, which would require providers to demonstrate capability of sending patient event notification, should have exceptions for all post-acute providers.**	Submitted by Vibra Healthcare (long-term care provider) **Provider-to-provider interoperability for post-acute care providers** **Provider-to-payer interoperability for post-acute care providers**

Post-Acute Care Providers

Comment	Submitter and Relevance
we strongly advise that CMS: A. Expand the scope and focus of its work, and prioritize the implementation and dissemination of semantically interoperable, standards-based health IT systems that can be used by nonphysician providers, including physical therapists in private practice, post-acute settings such as IRFs, skilled nursing facilities (SNFs), LTCHs, and home health agencies (HHAs); as well as by physicians, acute care hospitals, and other health care providers. Seamless, effective, and secure information-exchange practices enabled by such standards-based systems will improve health outcomes and enhance efficiency; and B. Provide financial and administrative implementation assistance for physical therapists in private practice and in post-acute settings such as IRFs, SNFs, LTCHs, and HHAs, and other provider types during the move to a more standardized and interoperable environment.	Submitted by American Physical Therapy Association (association) **Provider-to-provider interoperability for post-acute care providers** **Provider-to-payer interoperability for post-acute care providers**

Trusted Exchanges

Comment	Submitter and Relevance
We recognize the value of Trusted Exchange Networks. As such, we are supportive of the CMS proposal to require MA plans, Medicaid and HIP managed care plans, and QHPs in FFEs outlined by CMS are necessary. We support requiring the network to meet the following requirements: (i) Is capable of exchanging PHI, in compliance with all applicable state and federal laws across jurisdictions; (ii) Is capable of connecting to inpatient electronic health records and ambulatory electronic health records; and (iii) Supports secure messaging or electronic querying by and between providers, payers and patients. These efforts could help to improve interoperability.	Submitted by American Optometric Association (association) **Provider-to-provider interoperability** **Provider-to-payer interoperability**

Trusted Exchanges, cont'd…

Comment	Submitter and Relevance
HHSC OeHC recommends extending this date. OeHC however, is supportive of the use of a trusted exchange network because it shares methods of authentications and other ground rules for interoperability and leverages existing trusted exchange frameworks. The comment period for the proposed ONC Trusted Exchange Framework and Common Agreement rules ended in 2018, no final rule has been published. **Without the final rule for the TEFCA and the final rules regarding information blocking in place, Medicaid Managed Care plans and CHIP Managed Care entities would primarily exchange clinical data only with hospitals.** In a recent ONC update to Congress, it was reported in 2017 90% of non-federal acute care hospitals were electronically sharing information with health care providers outside of their organization and 61% can find patient health information from outside of their health system. The report compares the hospital percentages to 2015 percentages for office-based physicians, 48% and 34% respectively. Not been much improvement in provider connectivity has occurred. As a result, the data exchanged would likely include Admission, Discharge and Transfer (ADT) information and other standardized messages for public health reporting on MCO plans and CHIP entities respective patient populations. ADT and public health data could be used to supplement care coordination activities during Medicaid and CHIP client care transitions - impacting hospital readmissions, medication adherence, and future ED utilizations. Information on healthcare outcomes and other clinical patient data stored in office-based physician EHRs would be available once more office-based provider EHRs are connected and able to share data with the Medicaid plans and CHIP entities.	Submitted by American Optometric Association (association) **Provider-to-provider interoperability for post-acute care providers** **Provider-to-payer interoperability for post-acute care providers**

Proposed Rule Resources

- To read the CMS proposed rule and public comments, go to https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&D=CMS-2019-0039
- To read the ONC proposed rule and public comments, go to https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&D=HHS-ONC-2019-0002

Questions?

Q & A

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