PCPI Forum - June 5, 2019

The Future of Interoperability

Agenda

- Welcome and Housekeeping (5 minutes)
- Speaker Introductions (10 minutes)
- Presentation (25 minutes)
  - HHS Regulations: ONC and CMS
  - Stakeholders affected
- Question and Answer (15 minutes)
- On the Horizon (5 minutes)

Housekeeping

- This forum is being recorded

- All lines will be muted until the discussion

- This forum contains polls – you can participate using your mobile device or computer

- For the Q&A portion of the webinar, we will open the lines for discussion. Please remain muted unless you are speaking

Speakers and Discussants

Aisha Pittman, MPH
Measure Advisory Committee
Advocacy Advisory Committee
Premier

Kurt Skifstad, PhD
NQRN Advisory Committee
ArborMetrix

Chrystal Price
Associate Director, Registry Programs

Virginia Riehl
Consultant, Advocacy Advisory Committee

For discussion – We want to hear the Voice of the Member

- What steps are you taking to move towards collecting interoperable data?

- How does this regulation affect your providers? Your patients?

- Are you clear on the value of interoperability to your organization and your individual members?

- What are the largest perceived barriers to interoperability for your organization?

- What is the expected cost of these new regulations to your organization?

For discussion – We want to hear the Voice of the Member

- CMS/ONC sought comment on the inclusion of price information in the EHR. This aligns with the administrations overall initiative to increase price transparency.
  - How did your organizations respond to this proposals?
  - What obstacles do you see to increasing price transparency?
- How have you experienced information blocking to date? Do you believe the proposed rule will help resolve your data access needs
- What HIT challenges are you experiencing that you feel were not addressed in the rules?

HHS Sponsored Rules:

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955-AA01)

"ONC Cures Act"

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 (CMS-9115-P)

"CMS Interoperability Act"

Brief Background

- 21st Century Cures Act required DHHS to develop regulations to address patient access to their data, data blocking, and the use of APIs

- ONC and CMS issued proposed rules to advance these requirements
  - ONC rules focused on their role in regulating EHRs and in advancing interoperability
  - CMS focused on their role in regulating payments
  - Intention was to align the two NPRMs to be consistent and reinforce each other

How to join

Web

Did your organization submit comments on the ONC or CMS Rules on interoperability?

Yes, we submitted for both rules **A**

Yes, we submitted for ONC **B**

Yes, we submitted for CMS **C**

We did not submit any comments **D**

I don't know! **E**

Regulation Focus

ONC 21st Century Cures

- Data blocking

- Patient access to data

- Data standardization of Core Data for Interoperability

- Adoption of FHIR and APIs

- Requests for Information on:

  - Information exchange between providers and registries

  - Patient matching

CMS Interoperability Act

- Providing access to patient data for patients, clinicians, and hospitals

- Requiring payers to make patient data available

- Access to provider directories

- Adoption of APIs and FHIR

- Standardization of data with a focus on PAC

- Participation in trusted networks (TEFCA)

- Cross references to ONC regulation

Relevance to PCPI Members

- The lack of data availability and standardization increases the cost and complexity of sharing data for quality measurement

  - These regulations have the **potential** to advance the standardization of data and mandate that the data be shared

- BUT… these regulations were written without consideration of the perspective of quality measurement and registries with respect to data standardization and sharing

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955-AA01)

"ONC Cures Act"

ONC Cures Act– Applicability and Timeframe

Key Concern	PCPI Position
Lack of precision in the definition of the applicability of the regulation	PCPI suggests that ONC **refine the definition of who provides electronic health information**, clarifies which entities that will be affected by this regulation, and in particular considers that users, specifically _registries_ that have not been required to undergo ONC certification be excluded from this definition.
Ambitious implementation timeframes	We recommend that ONC consider a **staged approach to implementation** and work closely with electronic health information providers to create timeframes amenable to producing quality solutions.
Single Implementation Timeframe	We suggest that ONC **separate the processes and timeframes for clinicians and electronic health information entities** such as EHR vendors.
Providing Implementation Support	We encourage ONC to proactively **provide technical assistance** for those looking to develop and implement HL7-based APIs.

ONC Cures Act- Adoption of Standards

Key Concern	PCPI Position
Adoption of Consensus-Based Standards	In favor of **supporting standards that are created by consensus-based standards development organizations** to promote interoperability.
FHIR Maturity Concerns	Since FHIR is remains a nascent standard, we are concerned with the **need for additional testing** before it is fully functional and able to promote seamless data transfer.
Consistency of Standards Requirements Across ONC and CMS	We recommend proposed **coordination of common content and vocabulary standards across CMS and ONC** whenever possible.

ONC Cures Act – Data Standardization

Key Concern	PCPI Position
Registry and Quality Measurement Input to Common Data Elements	We **support further development of the USCDI through a consensus-based process that incorporates feedback from registries and quality measurement**. We also encourage ONC to work with other agencies to streamline and harmonize data concepts and vocabulary standards
Incorporation of Standards to Describe Data Context	We support inclusion of data that describes data being sent between entities, support inclusion of data that describes **provenance and provider demographics**, and support this within the context of the USCDI

ONC Cures Act – Data Access

Key Concern	PCPI Position
Information Blocking Exceptions in Practice	Broad-based exceptions to information blocking could be difficult to monitor and will allow electronic health information providers the **opportunity to withhold data from registries or to charge exorbitant fees for data exchange**
Need for a Standardized Format for Exporting Electronic Health Data	Making data export available without regulating its format is useful in theory but will result in data loss and poor data quality and increased costs in practice. We recommend that ONC promote **adherence to a standard for the transmission of data between health IT systems**

ONC Cures Act – Data Access

Key Concern	PCPI Position
Informing Patients of Data Available for Export	While it is important for ONC and other vendors to know what types of EHI can and cannot be exported, it is also important for patients to know this information as well. Therefore, we support the **inclusion of such language within patient portals and other communications received by patients** from their healthcare delivery organizations.
Burden Reduction for Patient Privacy and Access	We support protection of patient privacy, but we also strongly support **burden reduction for patients**. This includes notifying patients (via patient portals) of what EHI is eligible to be transferred and streamlining processes of data transfer. Patient burden reduction is a high priority and this could be compromised by prolonging data processing times and creating delays.
Timeframes for data transfer	We recommend that **ONC work closely with health IT providers to create guidelines for reasonable timeframes for transfer of data**.

ONC Cures Act --

Key Concern	PCPI Position
Single Standard for Clinical Quality Measures	We believe that ONC should consider permitting certification to one standard (either the 2019 CMS QRDA I Implementation Guide for Hospital Quality or the 2019 CMS QRDA III Implementation Guide for Eligible Professionals (EPs) and Eligible Clinicians, but not both.

In Conclusion – "ONC Cures Act":

- We support ONC's commitment to interoperability, however we believe regulatory guidance must be informed by the very entities governed by the regulation including **registries**.

- While ONC desires to cede most control of exchange of health information to health information providers, we recommend **ONC promote widespread adoption of standards** through a combination of regulatory and non-regulatory approaches.

- We recommend that promoted **standards are developed from consensus-based decision-making**

In Conclusion - "ONC Cures Act" continued

- Emerging standards such as **FHIR need rigorous testing in real-world applications** prior to inclusion in regulatory guidance.

- A **standard API infrastructure is essential** and significant support from a regulatory body is necessary for widespread adoption and conformance.

- We are broadly in concert with ONC on the information blocking policies proposed, however, we believe that the **broad-based exceptions to information blocking could be difficult to monitor and will allow electronic health information providers the opportunity to withhold data from registries or to charge exorbitant fees for data exchange**.
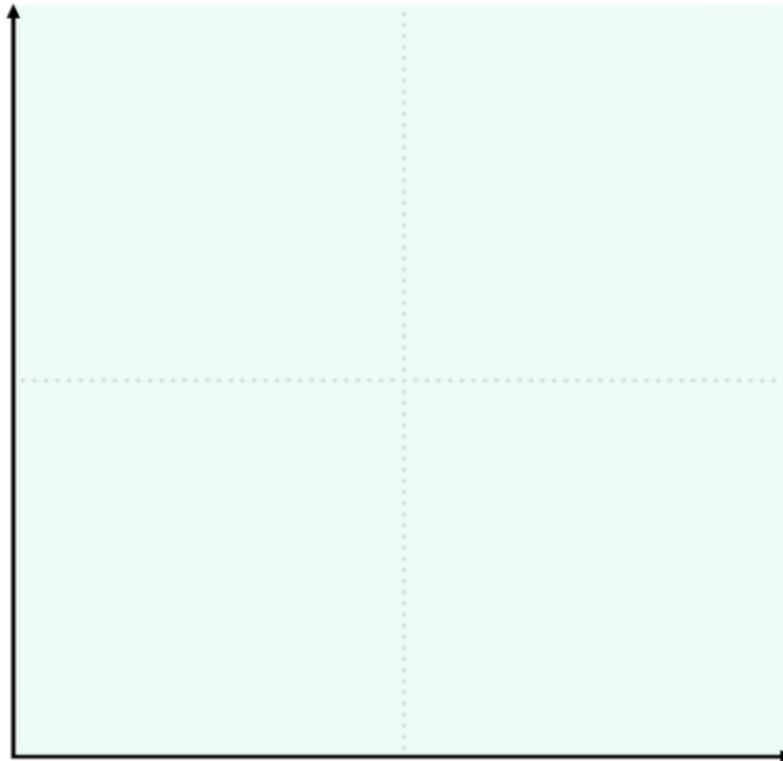
How to join

Web

① _____

② _____

Where does data interoperability fall in terms of urgency and importance to your organization? More important goes towards the top and more urgent goes to the right.

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"CMS Interoperability Act"

CMS Interoperability Act

Key Concern	PCPI Position
Alignment of ONC and CMS Requirements	We **support strong alignment and coordination with ONC and their regulatory requirements**. Variations in the clinical data definitions and semantic bindings will impede interoperability and increase the cost and burden of data capture, management, and sharing. amenable to producing quality solutions.
Incorporation of fully defined data definitions in FHIR	We recommend that the development of FHIR APIs is best achieved by **developing and maintaining a fully standardized set of clinical data models supported by both clinical and informatics consensus and review**. Joint development amongst consensus-based entities including standards development organizations that draw on the existing body of standards work is critical to maintaining these models**.**
Clarification of Application Programming Interface Standards	We request **clarification surrounding data requirements that are not fully encompassed in the ONC Cures Notice for Proposed Rulemaking**.

CMS Interoperability Act

Key Concern	PCPI Position
Compatibility Across Versions of Standards	The proposed rule states that it will allow entities to use updated standards if law does not impede the use and it does not disrupt a user's access to data, we are concerned that this could lead to issues of interpretation. We are concerned that the **definition as stated may allow *access* of a user's data but may not lead to *useable* data due to issues with backwards compatibility**.
Claims Data Availability	We support the data that has been outlined to be made available including patient claims and encounters data, provider directory data, clinical and laboratory data, and drug benefit data including pharmacy directory and formulary data.
Need for Further Definition of USCDI	We believe that the USCDI should be amended and further developed through a consensus-based standards development organization to allow this data to be used most efficiently and include metadata to aid in data validation.

CMS Interoperability Act

Key Concern	PCPI Position
Advancing Interoperability in Innovative Models	**We support incorporating interoperability-related issues into the development of innovative models**. Addressing interoperability as part of the tests in innovative models will reduce the barriers to the broader adoption of these approaches. We recommend that the data requirements for interoperability in innovative models be developed under a methodology and standards approach that **aligns with the USCDI** to ensure consistency in the interoperability standards that emerge from innovative models.

In Conclusion - CMS Interoperability Act

- We support CMS' commitment to interoperability, however we believe regulatory guidance must be informed by the very entities governed by the regulation.

- We believe a standard API infrastructure is essential and significant support from a regulatory body is necessary for widespread adoption and conformance.

Stakeholders affected: Clinicians and Providers

- Implementation timeline – too fast and married to that of EHI providers

- Privacy concerns – could increase liability for providers once patient information has been transmitted

- Adjustment of workflows to accommodate this new practice

Stakeholders affected: Registries

- Potential to be overregulated
- Lack of engagement and representation in the regulatory process
- Lack of structure and technical assistance for registries to participate in FHIR
- Structure of USCDI not inclusive of registry data
- Scope of information blocking is broad and inconsistent – prevents access to data
- Implementation timeframe – too fast

Stakeholders affected: Technology Vendors

- Implementation timeline – too fast

- Scope of EHI is too broad

- Scope of Information Blocking is inconsistent

- Lack of mature standards

Stakeholders affected: Patients

- Provisions to aid in access to data on care
  - Patient metadata transfer
- Security issues with third-party applications
- Patients are increasingly tasked with self-management of information
- Privacy vs burden
  - Data transfer needs to strike a balance between the two

Discussion

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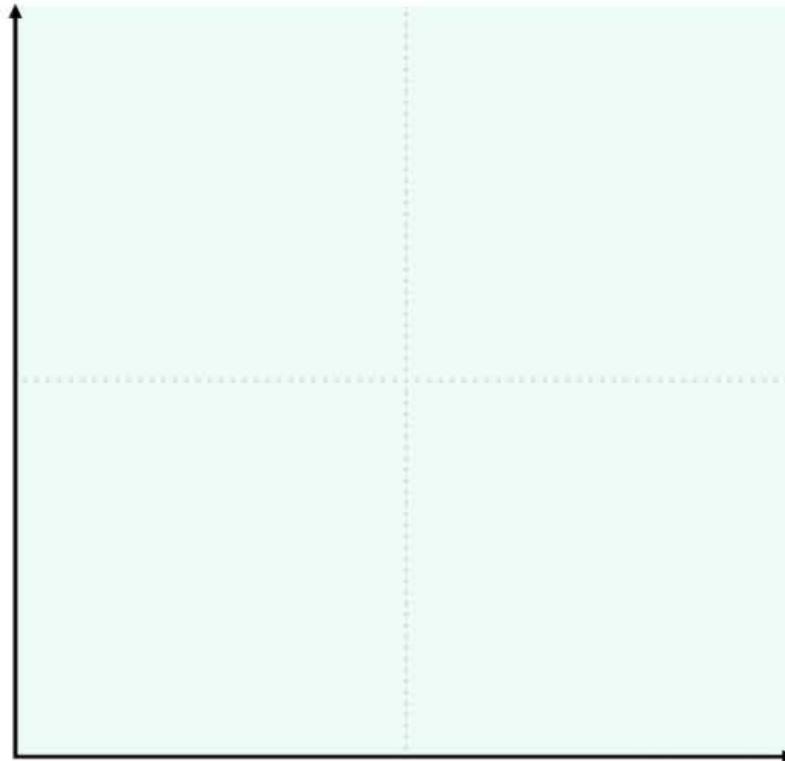Yes, we submitted for both rules

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On the Horizon...

- Advocacy Work

  - Member input period on IPPS Rule closes June 11th.

- Next Webinar

  - Physician Clinical Registry Coalition: Navigating the Legal Landscape for Measures

    - Monday, June 24, 2019

- PCPI Conference – November 10-12, 2019

  - The Quality Landscape: Charting the Course for Success

    - Data Makes the Difference

    - Population and Patient Centered Care

PCPI

The slides and recording will be posted at
http://thepcpi.org

Stay tuned to your email for updates.

For any questions please contact us at info@thepcpi.org