UPDATE ON MEANINGFUL USE NPRM & STANDARDS/CERTIFICATION IFR RELATED TO THE RECORD MANAGEMENT & EVIDENTIARY SUPPORT PROFILE

Update to the EHR WG January 19, 2010 (V2)

Purpose of the RM-ES Face to Face meeting:

- Disclaimer: These slides reflect the first meeting of the RM-ES profile group to evaluate the rule and are not the final analysis or recommendations. Please do not rely on this information solely, but use as a guide of potential issues to further explore.

- Evaluate key provisions in the following –
  - High level overview of regulation process and timeline
    - CMS - NPRM on Meaningful Use (MU)
    - ONC - IFR on Standards & Certification
  - Stage 1 definition and overview
  - Stage 1 standards and RM-ES applicability
  - Standards relationship to CMS Meaningful Use (MU)
  - RM-ES profile and how it supports MU
  - RM-ES profile and gaps in current functionality/conformance criteria

(Note: This applies to the US Realm)

Regulatory process overview/timeline

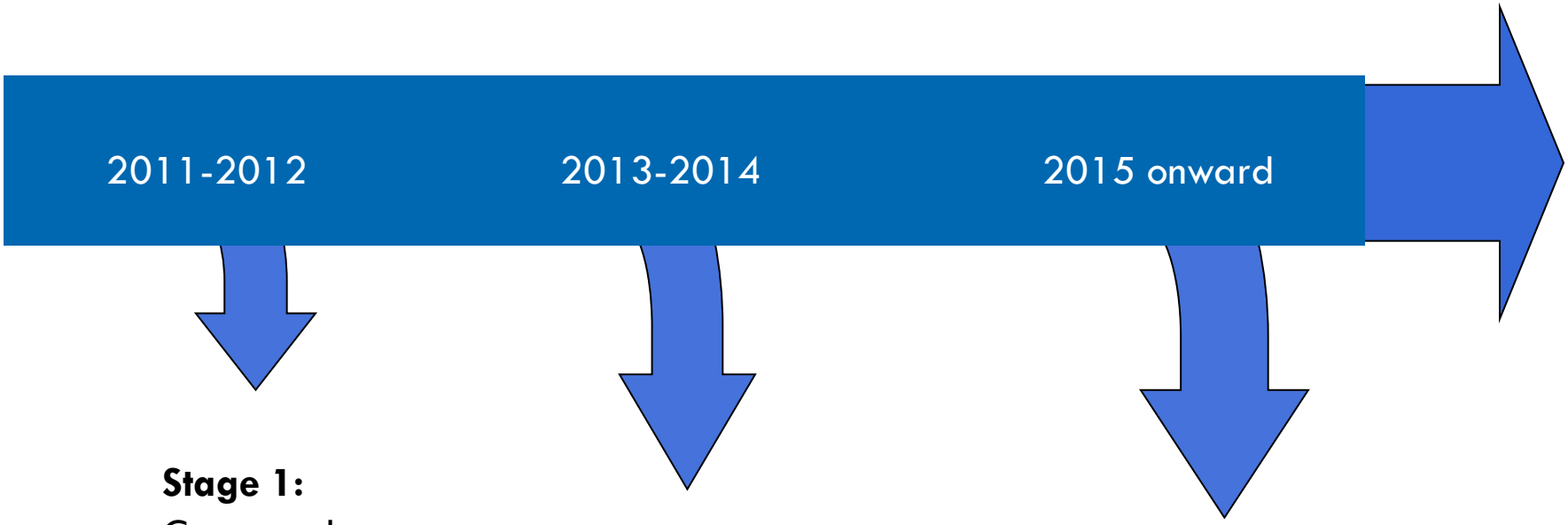
- CMS Notice of Proposed Rule Making (NPRM) for EHR Incentive Program
  - Defines the provisions for incentive payments to eligible professionals and hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified EHRs.
  - *Deadline for Public Comments is* ***March 13, 2010 for NPRM***
  - *Final Rule Released (tentatively) Late March, takes effective 60 days later*

- ONC Interim Final Rule (IFR) on Standards and Certification Criteria
  - Proposes initial set of standards, implementation specifications, and certification criteria to "enhance the interoperability, functionality, utility, and security of health IT and to support its meaningful use."
  - *Deadline for Public Comments is* ***March 13, 2010, which will impact Final rule.***
  - ***Interim*** *Final Rule Released 1/13/2010, effective 30 days later,* ***February 12, 2010.***

- ONC Rule on Certification Process (*forthcoming*)
  - Will address the process by which EHR systems will be certified or by which accreditation/certification entities can become recognized by CMS in order to certify EHR systems.

Source: Bobbi Bonnet, KP, 2010

Timeline for EHR "MU" functionality



Stage 1: Capture data in coded format

Stage 2: Expand exchange of information in the most structured format possible

Stage 3: Focus on reporting quality for high priority conditions, patient self management, and access to comprehensive data

Source: Bobbi Bonnet, KP, 2010

Standards Categories in EHR IFR

Content Exchange ***Standards used to exchange clinical information*** -clinical summaries (HL7 CCD or ASTM CCR) -prescriptions (NCPDP Script 5.0 or 8.1) -structure electronic documents (CMS PQRI 2008 Registry XML) (HL7 2.5.1 or 2.3.1) (HIPAA EDI code set) (CPT-4) (HL7 CVX)	**Vocabulary** ***Standardized nomenclature and codes sets*** -clinical problems (ICD-9-CM or SNOMED CT) -medications (RxNorm) -laboratory (LOIN-C) -allergies (TBD, but considering UNII)
Transport standards for HIE ***Establishment of communication protocols between systems*** -common, predictable, secure (SOAP v2.1 or REST)	**Privacy/Security** ***Establishment of standards to support*** -authentication (XUA or SAML) -access control (TBD) -transmission security (128 bit encryption, secure hashing algorithm [SHA-1] for transport of data) -audit log and disclosure accounting data capture

Source: Bobbi Bonnet, KP, 2010

Attachment A of June 2009 EHR TC Letter to ONC's HIT Policy Committee Attributes within MU NPRM (556 pages)

Patient Identify Validity

- W-Unique patients in the calculations for clinical measures.
- Weak -NPI for provider identity

User Authentication & Authorization

- None
- Weak-Exchange between 'authorized entities, authorized providers'
- Weak-States responsible for oversight (including Financial, Program Integrity, Provider Appeals).

Auditing (Metadata) and Validation Support

- None

Health Record Output

- Weak -in context of TPO disclosure report (metadata = date, time, patient ID, user ID, disclosure description

Attestation/Non-Repudiation

- None
- Weak-Infers that 'billing provider' is the only author
- Weak-References the potential to access vendor logs to determine validity of attested information for Medicaid
- Weak –Eligible Provider attests to the "accuracy and completeness" of clinical measures reported.

Alteration, Amendment, Correction

- Weak-Retain inbound data. Reference to "data payload for reporting quality measures" as output from EHR technology, references "such as CDA"

Source: ©Barbara Drury, Pricare 2010

MU Notations on EHR Documentation

- *Documentation of progress notes is a medical-legal requirement and a component of basic EHR functionality, and is not directly related to advanced processes of care or improvements in quality, safety, or efficiency.* (MU NPRM p. 53)
  - Documentation (medical-legal) is a component of basic EHR functionality
  - Documentation is not directly related to advanced processes of care
  - Documentation is not directly related to improvements in quality, safety, or efficiency

Source: ©Barbara Drury, Pricare 2010

Findings: Accounting of Disclosures

GAPS:

Accounting of Disclosure

Disclosure Management

Identity Management

Health Record Output

HIE

Diagnostic Support

Record Actions Related to EHI

- **Accounting of Disclosure**
  - What is the definition of disclosure under the rule?
  - What does the rule require?
  - What functions do we have currently in place?
  - What do we need to add?

Findings: Disclosure Management

- Accounting of Disclosure
- **Disclosure Management**
- Identity Management
- Health Record Output
- HIE
- Diagnostic Support
- Record Actions Related to EHI

- **Disclosure to Patients –**
  - Disclosure to PHRs
  - Timely access within 96 hours of the information being available to the eligible professional – (patient access)
    - Verify the patient to receive data within 48 hours for getting a summary of the record (a visit summary) [in the electronic copies to patients in their health summary]
    - Look into the discharge summary – need to define the source and the context
  - Evaluate rule for carve out situations for disclosure to the patients
    - Review EU work privacy rule interpretation
    - CBCC working on consent directive
    - No state preemption
    - Tie public comment responses to applicable HL7 standard(s)
      - What is the best standard based way to address

Finding: Identity Management

- Accounting of Disclosure
- Disclosure Management
- **Identity Management**
- Health Record Output
- HIE
- Diagnostic Support
- Record Actions Related to EHI

- **Identity Management – not specified to tie unique identifiers to a single patient record**
  - Critical to accomplish HIE
  - From a quality, patient safety, etc. this must be better specified; MU – did call some specifics

Finding: Health Record Output

- Accounting of Disclosure
- Disclosure Management
- Identity Management
- **Health Record Output**
- HIE
- Diagnostic Support
- Record Actions Related to EHI

- **Health Record Output**
  - EHRs FM does not specify CDA, CCD, CCR in Health Record Output function or criteria
  - Versioning could be an issue and underlying technology conversion compatibility – if a system is using a higher version of the CDA, CCD, etc. another entity not on that version may not be able to use it.

Findings: Health Information Exchange

Accounting of Disclosure

Disclosure Management

Identity Management

Health Record Output

HIE

Diagnostic Support

Record Actions Related to EHI

- **HIE Gaps**
  - Need comprehensive review of EHR-S FM in support of health information exchange
  - Release of Information functionality will need to be a component of the EHR system
  - Need ability to apply rules on disclosure (alcohol, behavioral health or HIV) – a master rules based engine that will have to apply the most restrictive rules for all of the participants
  - Evaluate current standards and maturity of the standards

Finding: Diagnostic Support

- Accounting of Disclosure
- Disclosure Management
- Identity Management
- Health Record Output
- HIE
- **Diagnostic Support**
- Record Actions Related to EHI

- **Diagnosis Support (Supportive)**
  - ICD-9-CM diagnoses and procedures; Includes the ability to put in a patient friendly description for PHR/PHI summaries or local descriptor along with the code.

Finding: Record Actions Related to EHI

Accounting of Disclosure

Disclosure Management

Identity Management

Health Record Output

HIE

Diagnostic Support

Record Actions Related to EHI

- Privacy & Security Standards
  - Audit Trail or metadata requirements for Record Actions Related to Electronic Health Information – Standards Rule (December version -page 85 table)
    - Gap in rule – doesn't require recording of "View" (did they assume viewing); extraction by other methodology (not printing)
    - Does the FM require recording of "printing"
    - Does not require retention – critical for monitoring privacy and security
    - Does not address ensuring that the audit is always on when in normal production
    - Does not secure the audit record – password protected, changes audited
    - Does not require exchange – is it necessary? (need to discuss further)
    - Does not require that it can be provided in a human readable format

Expansion of Certification Requirements for EHR Technology Beyond the Clinical Record

- Does the EHR-S FM need to reevaluate its definition of a system?
- The legislation has taken the view of an EHR to a very large scope
- RM-ES standards would apply to any of these modules that include PHI/records/data exchange
  - Billing, ADT, Claims – modules (Medisoft, Medical Manager, PCN, etc.)
  - Pharmacy IS
  - Patient Portals
  - HIE products
  - State immunization registries
  - CDS plug-ins
  - Payer Portals (formularies, eligibility, claims)

Metadata Issues with Calculating Metrics to be reported:

- Numerator/denominator calculations
  - Poorly defined for manual calculations
  - Poorly defined for vendor algorithms across systems with varying metadata
    - Mid-levels and signing authority vs 'billing provider ID'
    - NPRM sounds like 'claims-based' data
- Clinical Measures for specific specialties
  - Endorsed or authored by NCQA, NQF, etc. not always "important" in local setting,
  - Alignment among all requiring reporting (MCD, PQRI, Commercials, etc.
    - Providers need it
    - Vendors need it
- Is unique patient unique to the practice or unique to the physician for calculation of some measures
- This could be a nightmare for vendor calculation

Source: ©Barbara Drury, Pricare 2010

One View of "Unique Patient" Problems

Unique Patients	Pt A	Pt B	Pt C	Pt D	Pt E	Pt F	Pt G	Pt H	TOTAL = 8 Unique Patients for WHOLE practice.	problem list threshold 80%	reminders threshold 50%
Doctor 1 saw # times	4	0	2	0	0	6	0	0	3	2.4	1.5
Doctor 2 saw # times	0	7	0	0	3	1	1	0	4	3.2	2
Doctor 3 saw # times	1	1	1	0	1	3	2	0	6	4.8	3
									13		

1. Makes it look like the practice had 13 unique patients when in fact they had only 8 unique patients. Will some computer try to reconcile a true total of unique with the total of unique patients reported by each doc for the same practice? 2. Round up/round down? 3. Which provider gets credit for a complete registration that includes ethnicity and race? Not any part of an EMR and generally done on intake and done once.

# of unique patients that for ALL providers in this group.

Doctor 1's 3 unique patients made 12 visits. 80% = 2.4
Doctor 2's 4 unique patients made 12 visits. 80% = 3.2
Doctor 3's 6 unique patients made 9 visits. 80% = 4.8

Gap Analysis:170.210 – Standards for Privacy/Security and Accounting of Disclosure (CFR page 2044)

- Record actions (audit record) related to electronic health information
  - Date (IN2.2 cc3)
  - Time (IN2.2 cc3)
  - Patient identification (not specified – is it implicit?) DC.1 inherited function in the header includes 2.2 and that includes creation of a patient record
  - User identification
    - EHR-S FM specifies that users are not limited to humans (e.g. doctors). IN.1.1 cc1 - authenticate principals (i.e. users, entities, applications, devices, etc.)
    - IN2.2 – no CC requires the collection of the user in relation to EHI actions except for modification (IN.2.2 cc 9)

Gap Analysis: 170.210 – Standards for Privacy/Security and Accounting of Disclosure (CFR page 2044)

- Must be recorded when EHI is created, modified, deleted or printed and an indication of which action(s) occurred must also be recorded.
  - Created – IN2.2. cc3 (date/time)
  - Modified IN2.2. cc 4 (date/time); IN2.2 cc9 (author)
  - Deleted IN.2.2 cc8 (date/time)
  - **Printed** (GAP - not required in EHR-S FM)
  - **Accounting of Disclosure Requirements for Audit Data –**
    - 3 year retention
    - User ID (name or number)
    - Patient ID (name or number)
    - Date and Time
    - Disclosure Description – GAP in EHR-S FM
    - **Missing in the rule** – who the information is disclosed to
    - In an HIE Organization – with automated disclosure logic and computer to computer disclosure without an individual user disclosing – who is the user? (the computer, the healthcare entity?)
    - **Major Concern: Definition of treatment, payment and healthcare operations to understand what disclosures have to be tracked in an accounting of disclosure**

Gap Analysis:170.210 – Standards for Privacy/Security and Accounting of Disclosure (CFR page 2044)

- Missing from CFR that are in the EHR-S FM)
  - View (IN.2.2 cc ; IN2.2 cc10 – viewer)
  - Extraction (IN.2.2 cc ;
  - Exchange (IN.2.2 cc
  - Audit Report (IN2.2 cc
- Missing from CFR that and also **not** in the EHR-S FM
  - Who information was disclosure to
  - Retention of the audit record (accounting of disclosure required for 3 years in CFR
  - Useable report
- New Function for Accounting of Disclosure
  - Initially consider recommending a new child function in Supportive S.2.2.1 Health Record Output

Patient Identity Management – GAP in EHRS FM

- DC.1.1.1 (child function) of creating a record – NEW – should patient identity be mish-mashed with identification of patient records (we think this should be separated)
  - Research industry requirements
    - Probabilistic matching
    - Aliasing (also known as)
    - Masking of identity – VIPs and others
    - Merge and unmerge for ID (not just records)
    - Algorithms for identity matching

New Health Information Exchange Functionality

- Functionality of a release of information module should be explored for EHR systems
- Rules engine for disclosure needed
- Automated query and disclosure process
- Other
  - Merging of Medication Reconciliation Records (2011 Stage 1 requirement) – Potential R2 Gap
    - Example by Grady Memorial – they have an external entities data displayed in a different color
  - Traceability across multiple entities
    - Need to explore this further – Is entity A responsible for information sent to B and then entities B disclosed to (C, D & E)

General Talking Points on the Rules

- The government hasn't identified the baseline functionality for EHR technology to ensure end-to-end integrity of information – they have identified the minimum standards for exchange, but not the source system for the creation or management of electronic health information.
  - Without this standard patient safety is compromised – e.g. require merging medication reconciliation of two or more lists – compare and merge and create a new merged list (CFR – page 2028)
  - Health information exchange is only as valuable as the information being exchanged is reliable and accurate. If the source data can't be validated (non-reputable)
  - Patient safety will be compromised without addressing data integrity issues from the source through exchange

Next Steps

- Review the meeting notes with the full RM-ES profile group on January 25th
- Develop a subgroup to meet and develop talking points on key RM-ES issues related to the rules
  - Key messages
  - Comments related to specified standard requirements
- Identify suggestions for EHR-S FM R2 related to the rules for consideration
  - Gaps in functionality required by rules
  - Suggestions for addressing the gaps
- Timeline: 30 days (complete by mid/late February)

Thank You to the RM-ES Profile Group

Special thank you to Bobbi Bonnet, KP and Barbara Drury, Pricare, Inc., who analyzed the rules and developed the slides and presentations

RM-ES Profile Workgroup Meeting Information:

Meetings: Every other Monday (next meeting 1/25/10)

Time: 12 noon ET for 60 – 90 minutes

Dial-in: 770-657-9270

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