eCR Data Quality Subgroup

May 2023

Agenda

- eCR updates
- Timeboxing Diagnosis / Problem Rules in RCKMS
  - Shaily Krishan
- eCR in the HTI–1 Notice of Proposed Rulemaking
  - John Loonsk
- Questions and discussion

eCR Updates

- eICR CDA 3.1 support
  - Well formed CDA document should be processed by CDA supporting systems (while not all data may be mapped)
  - AIMS platform support for 3.1 should be finished in the next two weeks
  - Expect the most current version of the eCR Now FHIR App to support 3.1 by the end of June

- CSTE eCR Workgroup Call
  - May 16, 4-5 PM ET

Timeboxing Diagnosis / Problem Rules in RCKMS

Public Health eCR Data Quality Subgroup Meeting

May 9, 2023

What RCKMS Timeboxing is…

- Timeboxing is an effort to reduce the number of eICR messages that are determined to be reportable to PHAs based on Encounter Diagnoses or Problem list entries that may not be related to the current instance of disease.

- This is accomplished by including date-based logic in RCKMS rules to assess the interval between two key dates from the eICR message

RCKMS Timeboxing- Activity Recap

- Pilot Study (2022)
  - From August-September 2022, 4 jurisdictions participated in testing timeboxing for COVID-19 Diagnosis/ problem rules
  - Findings showed that timeboxing may reduce the number of eICRs received by about 13%
- January 2023
  - National eCR team collected PHA feedback for conditions & preferences for fixed/ variable timeboxing
  - 5 conditions / variable timeboxing
- February - May 2023
  - RCKMS administrators develop & test timeboxing functionality
  - Planned RCKMS technical deployment to enable the functionality (May 2023)

Timeboxing Definitions

Timeboxing = Evaluation of the duration between Date A* and Date B

- Date A = eICR Document Date*
- Date B = EffectiveTime/low of the current encounter (for Encounter Diagnosis) or of the Problem Concern Act Observation (for Active Problems)

Timebox Duration = the maximum acceptable interval between the two dates

2022 pilot used Date A = Start Date of Encompassing Encounter

<u>XPaths</u>

- eICR Document Date: ClinicalDocument/effectiveTime
- Diagnosis Date: ClinicalDocument/component/structuredBody/component/section/entry/encounter/effectiveTime/low
- Problem Date: ClinicalDocument/component/structuredBody/component/section/entry/act/entryRelationship/observation/effectiveTime/low

What RCKMS Timeboxing is not…

- Timeboxing will not change the content of eICRs; historical data in problem lists will remain in the eICRs if they are “unresolved.”
- Timeboxing will not eliminate “resolved” problems from eICRs (EHRs must exclude them for them to be eliminated).
- Timeboxing will only be applied to the criteria labeled “Condition Name (as a diagnosis or active problem),” for the primary condition. Timeboxing will not be applied to other problems, such as fever or cough.
- Initially, timeboxing will not be available for all conditions in RCKMS.

RCKMS Timeboxing – Initial Rollout

Initial conditions that will support timeboxing*:

- COVID-19
- Gonorrhea
- Hepatitis C Virus Infection
- Mpox
- Syphilis

**Timeboxing rules will be built on the latest versions of each condition*

Jurisdiction Administrators may enable/disable timeboxing in the tool for each condition that supports it (new versions will be available for selected conditions)

RCKMS Timeboxing – Initial Rollout

Default Behavior

When timeboxing support is added to a specific condition in RCKMS:

1. Timeboxing will be ***disabled*** by default.
2. With timeboxing disabled, RCKMS reportability determinations will be consistent with those determinations generated by the previous version of the condition.
3. Timeboxing will only be applicable to the criteria labeled “Condition Name (as a diagnosis or active problem),” for the primary condition.

RCKMS Timeboxing – Initial Rollout

Timebox Duration

Each condition that supports timeboxing will have a ***configurable Timebox Duration***.

- Different conditions may have different timebox durations (for example, Condition A = 3 weeks; Condition B = 3 months).
  - The RCKMS tool will not allow for a timebox duration shorter than 3 days
- Once enabled, the Timebox Duration will display on the Specifications tab in the authoring tool.
- Labels for timeboxed criteria in the RCKMS Authoring Interface will indicate which criteria are timeboxed and the timebox duration.
- Labels for timeboxed criteria in the Reportability Response will indicate which criteria are timeboxed and the timebox duration.

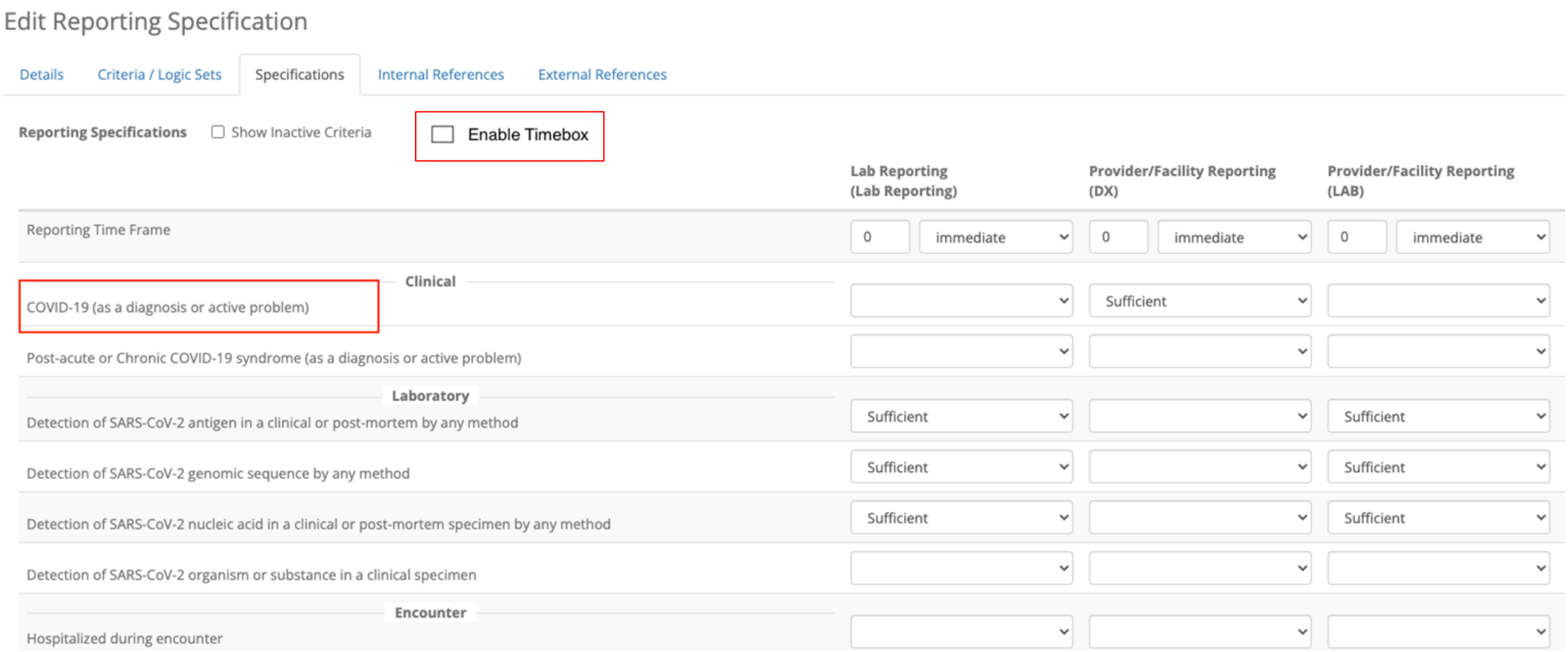
RCKMS Timeboxing – Initial Rollout

Application of Timeboxing

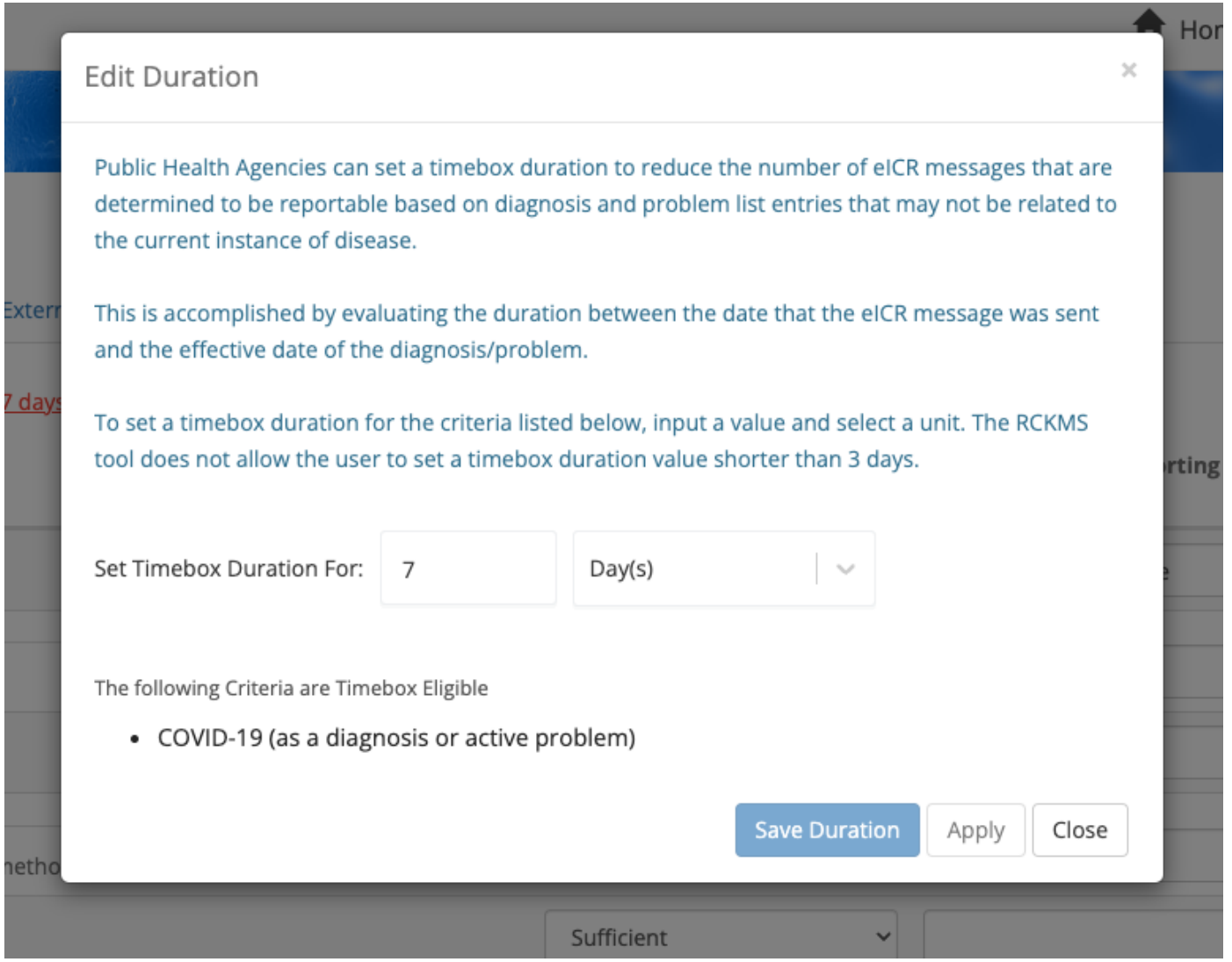
Timeboxing will apply to the criteria labeled **“Condition Name (as a diagnosis or active problem),”** for the primary condition. Timeboxing will not be applied to other problems. such as fever or cough.

	Lab Reporting (Lab Reporting)	Provider/Facility Reporting (DX)
Reporting Time Frame	0 immediate	0 immediate
Clinical		
COVID-19 (as a diagnosis or active problem)		Sufficient
Post-acute or Chronic COVID-19 syndrome (as a diagnosis or active problem)		
Laboratory		
Detection of SARS-CoV-2 antigen in a clinical or post-mortem specimen by any method	Sufficient	
Detection of SARS-CoV-2 genomic sequences by any method	Sufficient	
Detection of SARS-CoV-2 nucleic acid in a clinical or post-mortem specimen by any method	Sufficient	
Detection of SARS-CoV-2 organism or substance in a clinical specimen		
Encounter		
Hospitalized during encounter		

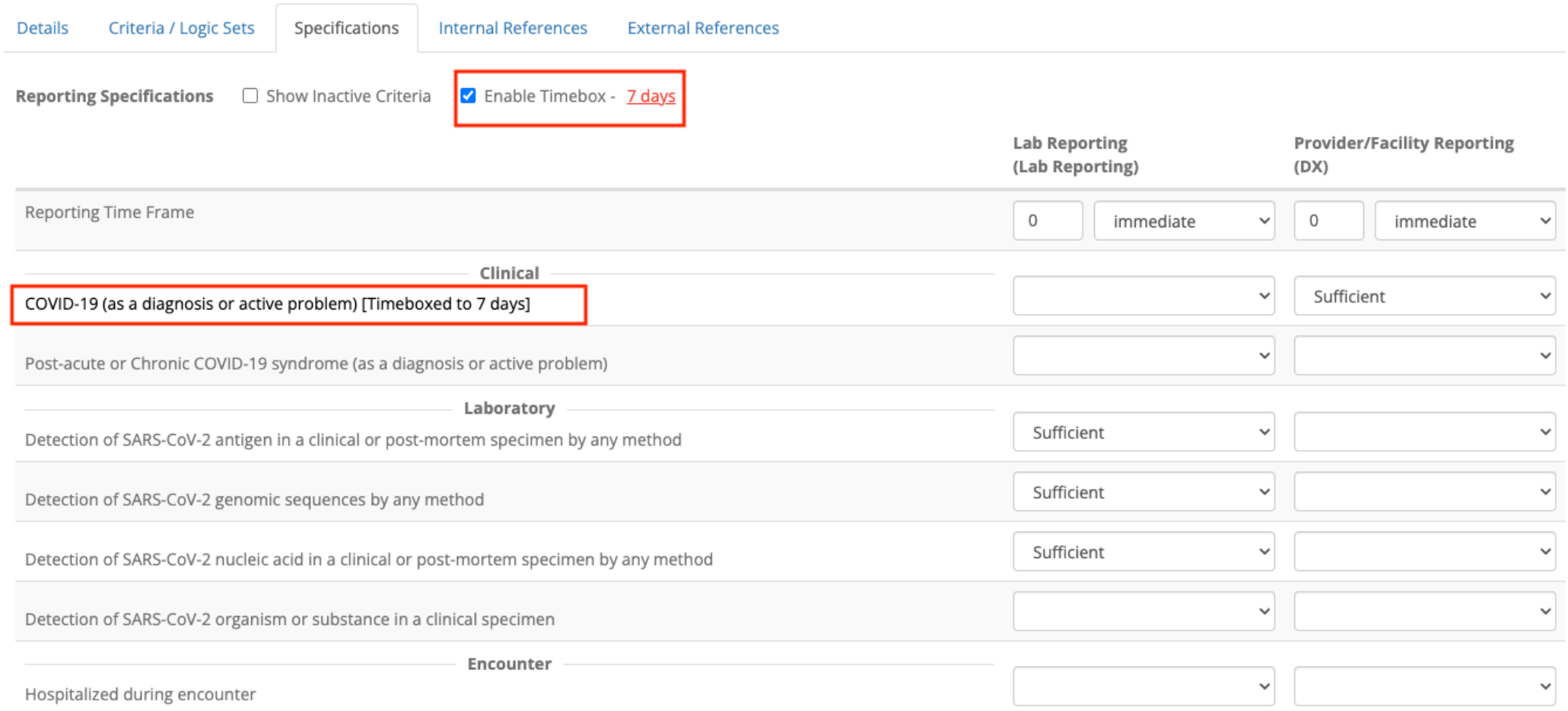
Timebox Criteria - Timeboxing NOT Enabled



Timebox Criteria - Setting the Duration



Timebox Criteria - Timeboxing Enabled



RCKMS Timeboxing – Initial Rollout

Timebox Calculation for Encounter Diagnosis

- The timebox is the acceptable difference between the *eICR Document Date* and the *Encounter EffectiveDateTimeLow* in the eICR message.
  - If this difference exceeds the condition's Timebox Duration value, RCKMS will return "No Rule Met" for the timeboxed criterion (Diagnosis or Active Problem).
- If *Encounter EffectiveDateTimeLow* is not present in the eICR, the timebox calculation will not be performed. The criteria will be processed as "Condition (as a diagnosis or active problem)," as though no timebox duration is set.

RCKMS Timeboxing – Initial Rollout

Timebox Calculation for Active Problems

- The timebox is the acceptable difference between the *eICR Document Date* and the *Problem Observation EffectiveDateTimeLow* in the eICR message.
  - If this difference exceeds the condition's Timebox Duration value, RCKMS will return "No Rule Met" for the timeboxed criterion (Diagnosis or Active Problem).
- If *Problem Observation EffectiveDateTimeLow* is not present in the eICR, the timebox calculation will not be performed. The criteria will be processed as "Condition (as a diagnosis or active problem)," as though no timebox duration is set.

RCKMS Timeboxing – Initial Rollout

Deployment Plans

1. Timeboxing software modifications will be released as part of the May 2023 deployment.
2. Reporting Specifications for the initial timebox-supported conditions will be made available in the RCKMS Authoring Interface via an off-schedule Content Release in June 2023.
3. RCKMS Administrators will import the initial set of updated Reporting Specifications on behalf of PHAs and ongoing authoring support will be available.
4. PHAs will decide whether/when to publish new timebox-enabled Reporting Specifications for their jurisdictions.

RCKMS Timeboxing- Initial Rollout Timeline

- Deployment to support Timeboxing modifications (RCKMS Admin use only, new versions of Reporting Specifications not yet available to users): **May 18th**
- Timeboxing Office Hours: **June 8th**
- **New Versions** of Reporting Specifications for the initial timebox-supported conditions available in the RCKMS Authoring Interface: **June 19th**
  - eICR test cases will be included to test timeboxed criteria (criteria test cases for testing the timebox function is not supported with the initial release)
  - Supporting materials available at www.rckms.org
- **Summer 2023:** Ongoing analysis of utility and functionality of initial rollout
- **Fall/ Winter 2023:**
  - Planning the extension of timeboxing for new and existing conditions going forward
  - Analysis of application of timeboxing to other types of RCKMS criteria (e.g., hospitalization, labs, etc.)

Discussion/ Questions

eCR in the HTI–1
Notice of Proposed Rulemaking (NPRM)

John Loonsk

Commenting on eCR in the HTI-1 NPRM

It is important that organizations / people comment on Notices of Proposed Rulemaking (NPRMs)

- In support of items
- With concerns about items when they exist
- To answer questions in the NPRM

Public heath associations frequently comment but many individual jurisdiction do / should as well

- The number of comments one way or another makes a difference

ONC did a great job with the eCR parts of HTI-1

- Most of the following is language that can be used to support the specific aspects of the NPRM that others may push back on
- If possible, please share all of the eCR language with those at your jurisdiction making comments or ask if you can help develop a letter yourselves
- Numbers do matter!

Commenting on eCR in the HTI-1 NPRM

- **Public comment period will end at 11:59 pm E.T. on June 20, 2023**
- ***Comments (or by hand):***
  1. *Federal eRulemaking Portal: http://www.regulations.gov.*
  2. *Regular, Express, or Overnight Mail (o*ne original and two copies)*:*

     Department of Health and Human Services, Office of the National Coordinator for Health Information Technology

     Attention: Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing Proposed Rule (RIN 0955–AA03)

     Mary E. Switzer Building, Mail Stop: 7033A

     330 C Street SW, Washington, DC 20201
- **The page number citations in the following are from:**
  - 2023-07229.pdf (govinfo.gov)

Supporting eCR in HTI-1

Citation in NPRM:

Page 23771

We propose a deliberate path towards greater standardization and specification of electronic case reporting, moving from functional requirements to standards-based requirements in § 170.315(f)(5) to improve consistency of implementations and interoperability over time.

- **Potential comments:**
  - ***ONC should be applauded for the work that has gone into the electronic case reporting (eCR) components of the HTI-1 NPRM. As it now stands, the language in the NPRM will help advance eCR for our state.***
  - ***We wholly support moving from "functional" certification to certification based on the consensus-based eCR standards and their use.***

Supporting eCR in HTI-1

Citation in NPRM:

Page 23772

We **invite comment** on our proposal to require that Health IT Modules certified to § 170.315(f)(5) support at least the eICR profiles of the HL7 FHIR eCR IG or the HL7 CDA eICR IG.

Potential comments:

- ***We understand the need to consider HL7 FHIR in keeping with industry directions, but eCR CDA support needs to continue. What is more, HL7 FHIR requires the same data and specificity as the CDA eCR standards. Public health needs to process these EHR data, needs continuity and consistency between the standards, and will need to be able to transform from one to the other.***

Supporting eCR in HTI-1

Citation in NPRM:

Page 23772

…we seek comment on whether we should instead require Health IT Modules to have the capability to receive, consume and process a reportability response formatted to both standards (RR profiles of the HL7 FHIR eCR IG and the HL7 CDA RR IG).

Potential comments:

- ***To help ease healthcare organization (HCO) and EHR burden we believe that they could choose to be certified to the Reportability Response (RR) format / standard that matches the eICR format that they are sending. They do not need to support both formats of the RR if they are only supporting one of the eICR formats / standards.***

Supporting eCR in HTI-1

Citation in NPRM:

Page 23773

Given that the contents of the RCTC value set update frequently, we propose to recognize the RCTC value set as a **minimum standard code set** in §170.205(t)(4), and we propose that the reference standard for the RCTC value set be established as RCTC OID: 2.16.840.1.114222.4.11.7508, Release March 29, 2022, IBR approved (incorporated by reference in § 170.299)

Potential comments:

- ***We understand the need to utilize a "minimum standard code set" for the RCTC value set and support its use in certification.***
- ***The eRSD exchange format for the RCTC value sets allows them to be electronically consumed. It also conveys important timing guidance for when eICRs should trigger and be reported. Public health needs to get an appropriate number of eICRs as defined by these parameters and has been challenged by getting too many and, on the other hand, possibly missing, important reports.***

Supporting eCR in HTI-1

Citation in NPRM:

Page 23773

We **request comment** on this approach and on whether there is general support of the eRSD Specification Library and eRSD Supplemental Library for electronic case reporting triggering.

Potential comments:

- ***We support the inclusion of consuming and processing the eRSD Specification Library and the eRSD Supplemental Library. During emergencies, new trigger codes are almost always needed and the more automated their consumption and inclusion is, the more rapidly and consistently they will be implemented. Rapid and consistent trigger code implementation is directly related to the effectiveness of their use in emergency response.***

Supporting eCR in HTI-1

Citation in NPRM:

Page 23773

We **invite comment** on the proposed adoption of the eRSD profiles for Health IT Modules …and our understanding that the eRSD profiles can be used by Health IT Modules that implement a CDA-approach to electronic case reporting.

Potential comments:

- ***We support the use of the FHIR eRSD specification for implementation in CDA systems as well as FHIR systems. An XML / JSON format is needed for consumption and processing and the FHIR specification might as well be the XML / JSON specification that is used.***

Supporting eCR in HTI-1

Citation in NPRM:

- Page 23771-2
- We reiterate that Health IT Modules would **need to follow the respective IG requirements for all ‘‘mandatory’’ and ‘‘must support’’ data elements** listed in each IG, as applicable. Specifically, by ‘‘mandatory’’ we mean support for data elements with minimum cardinality requirements equal to or greater than ‘‘1.’’ By ‘‘must support,’’ we mean ‘‘must support’’ as it is defined in the referenced HL7 FHIR implementation specifications. For equivalency of ‘‘must support’’ data in CDA IGs, a certified Health IT Module must support data elements with minimum cardinality requirements equal to or greater than ‘‘1’’ or a conformance verb of ‘‘SHALL’’ even if null values are allowed by the applicable data elements in the referenced CDA IGs.

Potential comments:

(Continued)

Supporting eCR in HTI-1

(Continued)

Citation in NPRM:

Page 23771-2

(Text in previous slide)

Potential comments:

- ***Referencing the eCR implementation guides is an important step in data quality, validation, testing, and completeness. The specificity of the implementation guides is critical to the advancement of the program. Implementation guide specificity is a complement to less granular laudable efforts like USCDI and USCDI+.***

Supporting eCR in HTI-1

Citation in NPRM:

Page 23772

We propose that certification to the updated criterion would be available for Health IT Modules upon the effective date of the final rule. In addition, because certification to § 170.315(f)(5)(i) would only be available through December 31, 2024, health IT developers with Health IT Modules certified to the § 170.315(f)(5) criterion based on meeting the requirements of § 170.315(f)(5)(i) would be **required to update and provide their customers with a Health IT Module updated to the revised certification criterion by December 31, 2024, to keep their certification to § 170.315(f)(5) active…**

Potential comments:

- ***We strongly support the recertification of all eCR implementors. The existing functional certification does not meet eCR program needs.***

Supporting eCR in HTI-1

Citation in NPRM:

Not in NPRM, but in existing certification companion guide.

Potential comments:

- ***Existing functional certification, in its certification companion guide, enables users of the eCR Now App to be deemed for certification. We have found that this is a useful function for Health IT developers and encourages consistent implementations.***
- ***We hope that the new certification process will also have a companion guide and also deem health IT developers that use the eCR Now App (of a reasonably current version) to fulfill these new certification criteria.***