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**Office of the National Coordinator
for Health Information Technology**

ONC Proposed Rule: Health Data, Technology, and Interoperability

Insights Condition and Maintenance of Certification Requirements (EHR Reporting Program)

May 11, 2023

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Insights Condition and Maintenance of Certification

| EHR Reporting Program | Insights Condition |

The Cures Act laid the foundation for transparent reporting

- Required establishing the Electronic Health Record (EHR) Reporting Program to measure the performance of certified health IT
- Specified the EHR reporting program be implemented as part of a Condition and Maintenance of Certification for certified health IT developers.

We refer to the EHR Reporting Program as the "Insights" Condition as that name better reflects its goals.

- Address information gaps in the health IT marketplace
- Provide insights on the use of specific certified health IT functionalities

The Basics

How Were the Measures Developed?

These first set of proposed measures focus on interoperability. ONC's contractor, The Urban Institute, developed a set of draft measures based on:

- Research, including market research;

- Input from stakeholders and health IT measurement experts; and

- Public feedback was obtained on the draft measures, including from the 2021 EHR Reporting Program Task Force of the HITAC.

The draft measures were revised based on HITAC and public feedback, along with additional research and feasibility testing, to create the current list of measures.

What Are the Measures?

AREA	MEASURE	RELATED CRITERION/CRITERIA	CRITERION NAME
Individual Access to EHI	Individuals' Access to Electronic Health Information Supported by Certified API Technology	§§ 170.315(e)(1); 170.315(g)(10)	VDT to 3rd Party, Standardized API for Patient and Population Services
Clinical Care Information Exchange	C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism C-CDA Medications, Allergies, and Problems Reconciliation and Incorporation Using Certified Health IT	§ 170.315(b)(2)	Clinical Information Reconciliation and Incorporation
Standards Adoption & Conformance	Applications Supported Through Certified Health IT Use of FHIR in Apps Supported by Certified API Technology Use of FHIR Bulk Data Access Through Certified Health IT	§ 170.315(g)(10)	Standardized API for Patient and Population Services
	Electronic Health Information Export (EHI) through Certified Health IT	§ 170.315(b)(10)	EHI Export
Public Health Information Exchange	Immunization Administrations Electronically Submitted to Immunization Information System Registries through Certified Health IT Immunization History and Forecasts	§ 170.315(f)(1)	Transmission to Immunization Registries

Who Will Be Reporting on These Measures?

- Developers of certified health IT would be expected to report (as required by each measure) if they meet the following criteria:
    - o They have at least 50 hospitals or 500 clinicians users <u>across</u> their certified health IT products; and
    - o Their product(s) are certified to the criterion/criteria associated with the measure; and
    - o The developer has <u>any users of the applicable criterion/criteria</u> associated with the measure.

- Otherwise, the health IT developer would report it does <u>not</u> meet the minimum reporting qualifications for that measure

What Information Will Be Submitted and How?

Measure results submitted should be aggregated or reported <u>at the product level (across versions)</u> in the format specified by the measure

- o For example, if there are 3 versions of a product, the measure submitted would reflect data across all 3 versions rather than reporting on each version separately.

Health IT developers shall <u>submit documentation</u> on the data sources and methodology used to generate submitted data

<u>Optionally</u>: Health IT developers may also submit descriptive or qualitative information to provide context as applicable

Submissions for the Insights Condition shall occur <u>via web-based form</u> and method, consistent with the requirement in § 3009A(c) of the PHSA, and <u>shall be made publicly available</u> via an ONC website
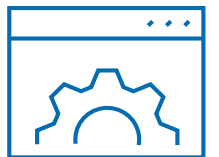
What Is the Reporting Frequency and Timeline?

Reporting of measures will be <u>phased in over two years</u>

- Year 1 will start with measures related to individual access, public health exchange and the applications supported through certified health IT measure

- Year 2 will follow with the rest of the measures

Year 1 (April 2025) Includes the following 4 measures:	Year 2 (April 2026) Adds the Following 5 Measures:
Individuals' access to electronic health information	C-CDA documents obtained using certified health IT by exchange mechanism
Applications supported through certified health IT	C-CDA medications, allergies, and problems reconciliation and incorporation using certified health IT
Immunization administrations electronically submitted to immunization information system registries through certified health IT	Use of FHIR in apps supported by certified API technology
	Use of FHIR bulk data access through certified health IT
Immunization history and forecasts	Electronic health information export through certified health IT

What Is the Reporting Frequency and Timeline?

Month																								
	Year 1												**Year 2**											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Reporting Periods				1st Reporting Period						2nd Reporting Period			3rd Reporting Period									4th Reporting Period →		
Generating Measures during "Assembly" Periods				*Collect Data*						1st Assembly Period			2nd Assembly Period									3rd Assembly Period →		
															Assemble Data									
Reporting window coincides with Condition & Maintenance of Certification																1st *Report Data*						2nd		

- Developers of certified health IT shall submit measures <u>every six months</u>
  - Reporting aligned with the Attestations Condition and Maintenance of Certification
    - Submission windows: April 1 – 30; October 1 – 31

Request for Comment

- Overall program processes
  - Frequency of reporting
  - Phased approach and timeline (starting in April, 2025)
  - Submission process and mechanism for reporting

- Thresholds to set minimum qualifications for the Insights condition
  - These were set based upon data available to ONC

- Other issues
  - Specific hardships health IT developers of certified health IT may encounter

Proposed Measures

Format of Measures

- **Varied types of measures**
  - Numerators and denominators
    - Several numerators/denominators allow for generating multiple metrics
  - Same denominators for some measures
  - Simple lists of data, counts and/or attestations

- Reporting consists of what is called for in the measure (e.g., numerator, denominator, counts, attestation) <u>not</u> generation of percentages or other metrics

- **Some measures call for stratification. What do we mean by that?**
  - Stratifying involves breaking out the numerator and/or denominator by a particular category.

Measure Topic Area: Clinical Care Information Exchange

The measure "C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism" captures the volume of Consolidated C-CDA documents obtained via different exchange mechanisms relative to patient volume.

What are the methods being used to obtain C-CDAs?

To what extent are C-CDAs obtained in relation to patient volume?

?

Benefit: Shed light on how certified health IT supports exchange of health information in relation to patient volume.

Measure Topic Area: Clinical Care Information Exchange

The measure "C-CDA Problems, Allergies and Medications Reconciliation and Incorporation Using Certified Health IT" captures the extent to which C-CDA documents that have been obtained are subsequently reconciled and incorporated as part of a patient's record.

What are the methods being used to obtain C-CDAs?

To what extent are C-CDAs shared as part of an encounter?

?

To what extent are C-CDAs obtained, subsequently used?

?

Benefit: Shed light on how certified health IT supports the use of external information by providers.

Measures: Clinical Care Information Exchange

C-CDA Documents Obtained Using Certified Health IT by Exchange Mechanism	C-CDA Problems, Allergies and Medications Reconciliation and Incorporation Using Certified Health IT
Denominator(s)	
1. Number of encounters during the reporting period. 2. Number of unique patients with an encounter during the reporting period. 3. Number of unique patients with an associated C-CDA document during the reporting period. 4. Number of unique C-CDA document obtained using certified health IT during the reporting period.	
Numerator(s)	**Numerator(s)**
Number of unique C-CDA documents **obtained** during the reporting period using certified health IT via the following different methods: • Direct Messaging • Local/regional health information exchange (HIE) or national health information network • Developer-specific health information network • Method not listed above excluding electronic fax	1. Number of C-CDA documents of Continuity of Care Document (CCD), Referral Note, and Discharge summary types that are obtained and incorporated across all exchange mechanisms supported by certified health IT during the reporting period.

Potential Metrics That Can Be Derived From Data:

- The percent of unique C-CDA documents obtained by method

- Percentage of patients (with an encounter) who had an associated C-CDA document

- Percentage of total number of C-CDA documents (CCD, Referral Note and Discharge Summary) incorporated among those obtained

- The total number of C-CDA documents (CCD, Referral Note and Discharge Summary) obtained and incorporated per encounter

Request for Comment: Clinical Care Exchange Measures

- Reduce number of exchange mechanisms for the C-CDA exchange measure
  o Combine all types of networks into one category (including developer networks)
  o Combine Direct Messaging and Other Methods into one category

- Value of focusing on CCD, Referral Note, Discharge Summary for the C-CDA incorporation measure

- Duplication of C-CDAs
  o Can meaningful measures be obtained without de-duplication of C-CDAs?
  o How often are duplicate C-CDA documents obtained by customers of certified health IT?
  o How much of a burden it will impose on developers of certified health IT to ensure that C-CDA documents are not duplicates?

Measure Topic Area: Standards Adoption and Conformance

The measure "Applications Supported Through Certified Health IT" captures how certified health IT is supporting the app ecosystem.

Benefit: Provide greater transparency regarding the apps that are connected to certified health IT.
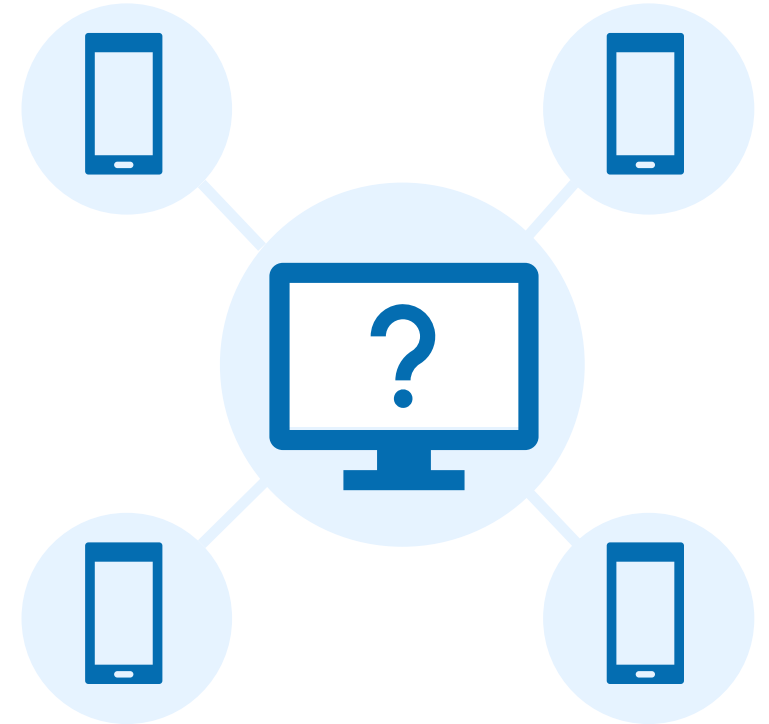
What apps are connected to certified health IT products?

Measure: Standards Adoption and Conformance

List
• **Application Name**
• **Developer** (company/organization or individual) responsible for the app

• **Intended Purpose of App** Using the Following Categories:
  ○ Administrative Tasks (e.g., scheduling & check-in, billing & payment)
  ○ Clinical Tools (e.g., clinical decision support, risk calculators, remote patient monitoring)
  ○ Individuals' Access to their EHI (e.g., enables patients to access their health information, medications, test results, vaccine records)
  ○ Research (e.g., used to perform clinical research)
  ○ Population Data (e.g., bulk transfer of data, population analytics & reporting)
  ○ Public Health (e.g., electronic case reporting)
  ○ Patient-Provider Communication (e.g., secure messaging, telehealth)
  ○ Educational Resources (e.g., patient and provider educational resources)
  ○ Other Intended Purpose
  ○ Unknown (e.g., missing)

• **Intended User of App** Using the Following Categories:
  ○ Individual/Caregiver
  ○ Clinician
  ○ Health Care Organization
  ○ Payer
  ○ Researcher
  ○ Other Intended User
  ○ Unknown (e.g., missing)

• **Status of App** Using the Following Categories:
  ○ Actively Used (EHI transferred for 10+ unique patients during reporting period)
  ○ Not Actively Used (EHI transferred for <10 unique patients during reporting period)

Potential Metrics That Can Be Derived From Data:

- Percentage of apps that are in active use
- Percentage of apps by user type
- Percentage of apps by intended purpose
- Percentage of apps that are in active use by user type
- Percentage of apps listed across products

Measure Topic Areas: Standards Adoption and Conformance

- The measure "Electronic Health Information (EHI) Export Through Certified Health IT" captures the use of certified health IT to export single patient and patient population EHI.

- The measure "Use of FHIR Bulk Data Access Through Certified Health IT" captures the volume of bulk data downloads relative to the number of certified health IT deployments.
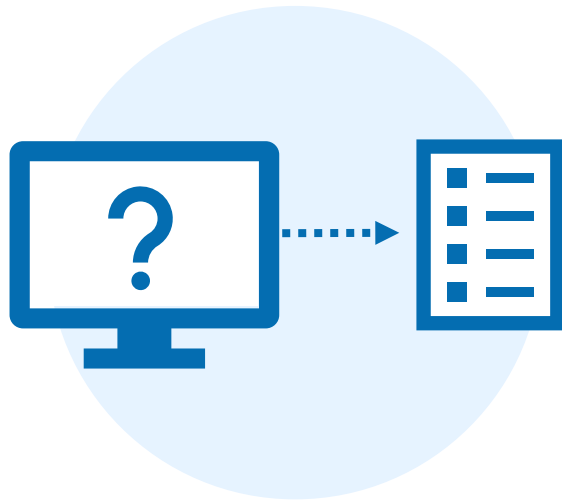
To what extent are EHI export and Bulk FHIR capabilities being used to support the movement of data from EHRs?

Benefit: These measures shed light on how functions that enable the export and respond to requests to download of data are used in certified health IT.

Measures: Standards Adoption and Conformance

Electronic Health Information Export

Attestation

"We enable direct-to-individual EHI exports"
- "Yes"
- "No"

Count

The number of full data EHI export requests processed during the reporting period.

Stratifications

The count should be reported by the following subgroups:
- Single patient EHI export
- Patient population EHI Export

Potential Metrics That Can Be Derived From Data:

- Count of full data EHI export requests processed by single patient vs. patient population requests

- Percentage of products/modules certified to (b)(10) that support direct-to-individual EHI exports

Measures: Standards Adoption and Conformance

Use of FHIR Bulk Data Access

Denominator
Number of distinct certified health IT deployments or installations (across clients).

Numerators
1. Number of bulk data/download requests completed during the reporting period using certified health IT* in response to a bulk data download request <u>to export all data for patients</u> within a specified group. 2. Number of distinct certified health IT deployments or installations* across clients that <u>successfully completed at least one bulk data download request</u> during the reporting period.

Note: *Certified to the "standardized API for patient and population services" (§ 170.315(g)(10))

Potential Metrics That Can Be Derived From Data:

- Rate of bulk data download requests successfully completed per certified health IT deployment.

- Percent of certified health IT deployments with at least one successfully completed bulk data download request.

Measure Topic Areas: Standards Adoption and Conformance

The measure "Use of FHIR in Apps Supported by Certified API Technology" captures the volume of FHIR resources transferred in response to API calls from apps connected to certified API technology by FHIR resource type.
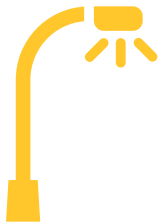
Benefit: These measures shed light on the uptake, implementation and use of FHIR in certified health IT.

What is depth and breadth of FHIR usage?

Measures: Standards Adoption and Conformance

Use of FHIR in Apps Supported by Certified API Technology

Denominator
Number of distinct certified API technology deployments (across clients).

Numerators
1. Number of FHIR resources returned/transferred in response to a call by resource type. 2. Number of distinct certified API technology deployments (across clients) associated with at least one FHIR resource returned/transferred in response to a call.

Stratifications

Denominator and Numerators:
○ Type of endpoint
  ▪ Patient-facing
  ▪ Non-patient-facing
○ FHIR version
○ U.S. Core Implementation Guide version

Potential Metrics That Can Be Derived From Data:

○ Percent of FHIR resources returned/transferred by resource type

- Broken out by stratifications listed

○ Percent of certified API technology deployments where at least one FHIR resource was transferred

- Broken out by stratifications listed

Use of FHIR in Apps Supported by Certified API Technology Measure Numerator Example

	Type of Endpoint		U.S. Core Implementation Guide		FHIR Version	
	Patient-Facing	Clinician-Facing	**v1**	**v2, etc.**	**STU3**	**R4, etc.**
Number of distinct certified API technology deployments which returned at least one FHIR resource in response to a call.						

Request for Comment: Standards Adoption & Conformance

Applications Supported Through Certified Health IT Measure

- Categories to characterize apps

- Definition of "Active use" status (EHI transferred for 10+ unique patients during reporting period)

EHI export through certified health IT measure

- What is the value and level of effort for this measure to be reported by:
  - Intended use case (e.g., moving to another certified health IT system, use for a population health tool)?
  - Types of recipients (e.g., patients, organizations) of the exported data)?

Use of FHIR Bulk Data Access through Certified Health IT Measure

- What is the value and level of effort for this measure to be reported by:
  - Intended use case (e.g., population analytics, reporting, research)
  - Type of entity calling the API (e.g., healthcare organization, payer, public health agency)
  - Number of automated queries (refreshing the data at certain intervals) vs. ad hoc queries?
- What is the value and level of effort in reporting on the number of authorized users calling a bulk FHIR API?

Use of FHIR in Apps Supported by Certified API Technology

Are both the FHIR version and U.S. Core Implementation Guide necessary or would one of these be sufficient for understanding the implementation of FHIR? If just one, which one?

Measure Topic Area: Individual Access to EHI

The measure "Individual Access to Electronic Health Information" would capture different methods individuals use to access their EHI including:

- Third-party app technology certified to "standardized API for patient population services" certification criterion under § 170.315(g)(10);

- Apps offered by the health IT developer or health care provider using technology certified to the API criterion under § 170.315(g)(10) (if applicable); or

- Patient portal technology certified to the "view, download, and transmit to 3rd party" certification criterion under § 170.315(e)(1) only

Benefit: Help refine and assess policies that have sought to increase individuals' access to their EHI.
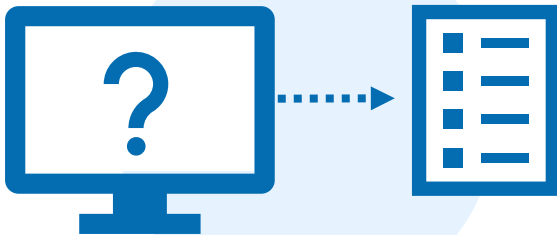
What methods are individuals using to access their EHI?

Measure: Individual Access to EHI

Individual Access to EHI

Denominator(s)
1. Number of unique individuals who had an encounter during the reporting period.
2. Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period using at least one of the three types of methods.
3. Number of unique individuals who accessed their EHI using at least one of the three types of methods during the reporting period regardless of whether the individual had an encounter or not.

Numerator(s)
1. Number of unique individuals who had an encounter and accessed their EHI at least once during the reporting period using at least one of the three types of methods.
2. Number of unique individuals who accessed their EHI using at least one of the three types of methods during the reporting period regardless of whether the individual had an encounter or not.

Stratifications
Numerator 1 and 2: Type of Method to Access EHI

Potential Metrics That Can Be Derived From Data:

- Percent of individuals with an encounter who accessed EHI by at least one type of method (overall)
  - Percent of individuals with an encounter who access EHI by the type of method
- Percent of all individuals who access EHI by at least one type of method
- Percent of all individuals who access EHI by the type of method

Measure Topic Area: Public Health Information Exchange

The measure "Immunization Administrations Electronically Submitted to Immunization Information System Registries (IIS) through Certified Health IT" would capture the use of certified health IT to send information on vaccination and immunization administrations to an IIS registry.

The measure "Immunization History and Forecasts" captures the use of certified health IT to query information from an IIS registry.

Benefit: Inform public health preparedness by providing insights into the use of certified health IT to exchange vaccination/immunization data with IIS registries

To what extent are vaccine administrations successfully submitted to an IIS using certified health IT?

To what extent are immunization queries made of an IIS successfully responded to/received via certified health IT?

Measures: Public Health Information Exchange

Immunization Administration Electronically Submitted to IIS	Immunization History and Forecasts
Denominator(s)	**Denominator(s)**
The number of immunizations administered during the reported period.	1. The number of immunization queries sent during the reported period. 2. The number of encounters during the reporting period.
Numerator(s)	**Numerator(s)**
The number of immunization administrations from which the information was electronically submitted to an IIS registry successfully during the reporting period.	The number of query responses successfully received from an IIS during the reporting period.
Stratifications	**Stratifications**

Denominator and Numerator:
• IIS
• Age Group
  • Adults = 18 years and over
  • Adolescents/infants = 17 years and under
	Denominator 1 and Numerator:
	• IIS
	• Age Group
	  • Adults = 18 years and over
	  • Adolescents/infants = 17 years and under

Potential Metrics That Can Be Derived From Data:

- Percent of immunizations administered where the information was electronically submitted to an IIS registry

- Percent of immunization forecast queries responses from an IIS electronically received among all queries sent.

- Percent of immunization forecast queries responses from an IIS electronically received among all patient encounters.

Request for Comment: Immunization Administrations Electronically Submitted to an Immunization Information System through Certified Health IT Measure

- **Successful submission to an IIS**
  - Definition of "successful" submission to IIS would be the total number of messages submitted minus acknowledgments with errors (2.5.1, severity level of E). We propose that ACKs with an error (severity level of E) would not be counted. **Should ACKs with a warning (severity level W) be counted in the numerator?**
  - For providers who operate in multiple states, and thus would be sending data for the same administration to multiple IISs, **should a successful submission should be counted if a provider is able to successfully submit to at least one registry versus all the registries to which the provider submitted**?
  - We are also considering whether "replays," which involve resubmitting administrations until they are successfully submitted, qualify as a successful submission. **Should successful submissions be limited to the first attempt to submit or should "replays" qualify as a successful submission**?

- **Should adolescents/infants should be further stratified by age, and by what age limits?**

- **Can the number of immunizations administered be linked to immunizations submitted to the IIS,** effectively creating a subset of the numerator (immunizations administered)?

Request for Comment: Immunization History and Forecasts Measure

- The definition of a "successful" response/receipt from an IIS should be the total number of messages submitted minus acknowledgments with errors (2.5.1, severity level of E).
  - HL7 Z42 messages contain both immunization history and forecast, whereas Z32 messages exclusively contain history. **Should both message types should be included in the measure numerator?**

- Exclusion/Inclusion criteria
  - Given that it is unlikely that IIS queries happen for every patient encounter, **should the second denominator (#encounters) capture the total number of applicable patient encounters during the reporting period regardless of whether a query was sent to an IIS?**
  - Currently, we are proposing that developers of certified health IT with Health IT Modules certified to § 170.315(f)(1) would attest that they are unable to report on this measure if they have no users that administered immunizations during the reporting period. However, there may also be providers who do not administer immunizations but would want to query an IIS to determine whether their patient has received a vaccination. **We seek comments on whether we should include this exclusion or suggestions on how we could better refine it.**

- **Should adolescents/infants should be further stratified by age, and by what age limits?**

Request for Comment: Definition of Encounters (applicable to clinical exchange, Individual Access and Immunization Measures)

- Definitions of Encounters based on the National Committee for Quality Assurance (NCQA) outpatient value set and SNOMED CT inpatient encounter codes listed below which were recommended by the HITAC and Urban Institute.
    - Emergency department patient visit (procedure) – 4525004
    - Emergency hospital admission (procedure) – 183452005
    - Hospital admission (procedure) - 32485007
    - Hospital admission, elective (procedure) - 8715000
    - Admission to observation unit (procedure) - 448951000124107

- We seek comment on whether to define encounters in this manner, or include any type of visit (e.g., all encounters) in the measure denominator.

- Additionally, we seek comment on alternative approaches to measuring encounters.

Resources Available on HealthIT.gov!

Visit https://healthIT.gov/proposedrule for additional information. More updates will be added over time.

Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions
- Information Blocking
- **Insights Condition**
- "Update and Provide" Certification Requirements

How to Submit a Comment

Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA03, through http://www.regulations.gov. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.
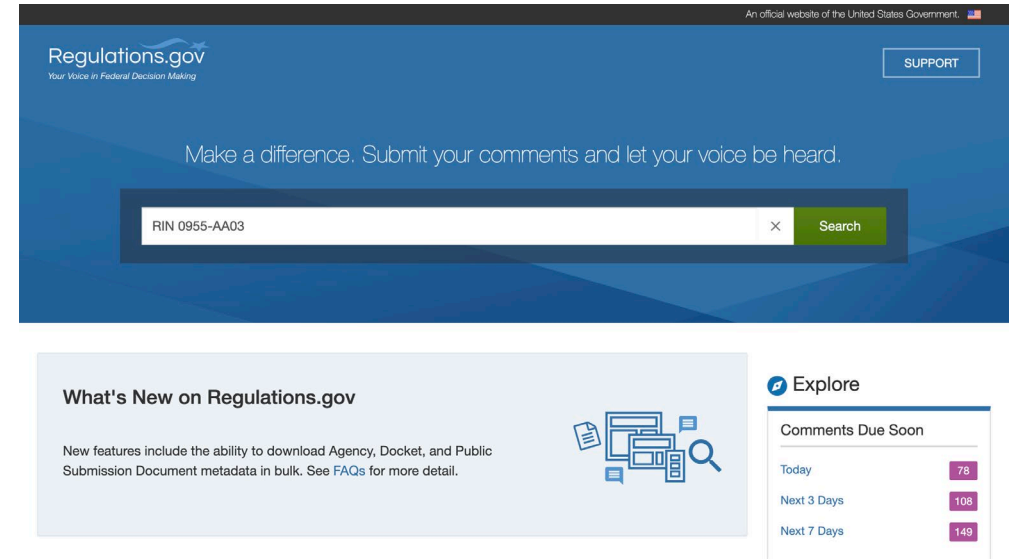
Public Comment Template

We will provide a template following publication of the proposed rule in the Federal Register for the public to use, if they so choose, when submitting their comments.

ONC Project Tracking System

The Measure Specification Sheets (MSS) Issue Tracker on the ONC Project Tracking System is for the public to review and provide comment on the technical specifications and calculations supporting the proposed measures related to the Insights Condition and Maintenance of Certification requirements. Visit https://oncprojectracking.healthit.gov/support/projects/MSS/summary

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Appendix

Thresholds for Minimum Qualifications

Table 3—Thresholds Options at the Developer Level

	Est. number of users only using small developers	Est. % of users only using small developers	Est. number of small developers	Est. number of remaining developers
Hospitals:				
Option (a) 100 Threshold	142	3.7	39	12
Option (b) 50 Threshold	56	1.4	33	18
Clinicians:				
Option (a) 2,000 Threshold	21,075	3.1	176	31
Option (b) 1,000 Threshold	11,251	1.6	160	47
Option (b) 500 Threshold	7,828	1.1	146	61

Data Source: ONC analysis of 2019 CMS Promoting Interoperability Program Data & CHPL.

Use of FHIR in Apps Supported by Certified API Technology Measure Numerator Example

	Type of Endpoint		U.S. Core Implementation Guide		FHIR Version	
	Patient-Facing	Clinician-Facing	v1	v2, etc.	STU3	R4, etc.
Resource	#Data returned/ Transfers	#Data returned/ Transfers	#Data returned/ Transfers	#Data returned/ Transfers	#Data returned/ Transfers	#Data returned/ Transfers
Patient						
Practitioner						
Observation, etc.						