

# Overview of the Final Interoperability and Information Blocking Rules

May 21, 2020



Association of  
American Medical Colleges

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## ONC and CMS Health IT Final Rules

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## General Information on Final Rules

ONC “21<sup>st</sup> Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program” Final Rule and CMS “Interoperability and Patient Access” Final Rule were published in the Federal Register on May 1, 2020 ([85 FR 25642](#) [ONC] and [85 FR 25510](#) [CMS])

Final rules are effective 30 June 2020, though certain policies may have different dates specified for implementation and/or enforcement.

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## Major Finalized Policies – ONC Rule

- Information Blocking
  - Definitions
  - Exceptions
  - Penalties
- Updating 2015 Edition Certification Criteria
  - EHI Export
  - Application Programming Interfaces (APIs)
- Conditions and Maintenance of Certification
  - Implementation
  - Provisions (Info Blocking, Assurances, APIs, etc.)
  - Compliance & Enforcement

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## Major Finalized Policies – CMS Rule

- New Conditions of Participation (CoPs) for Hospitals and CAHs
  - Requirements for ADT notifications
  - Compliance
- Information Blocking and Public Reporting
- Provider Digital Contact Information
- Patient Access Through APIs
- Health Information Exchange and Care Coordination Across Payers

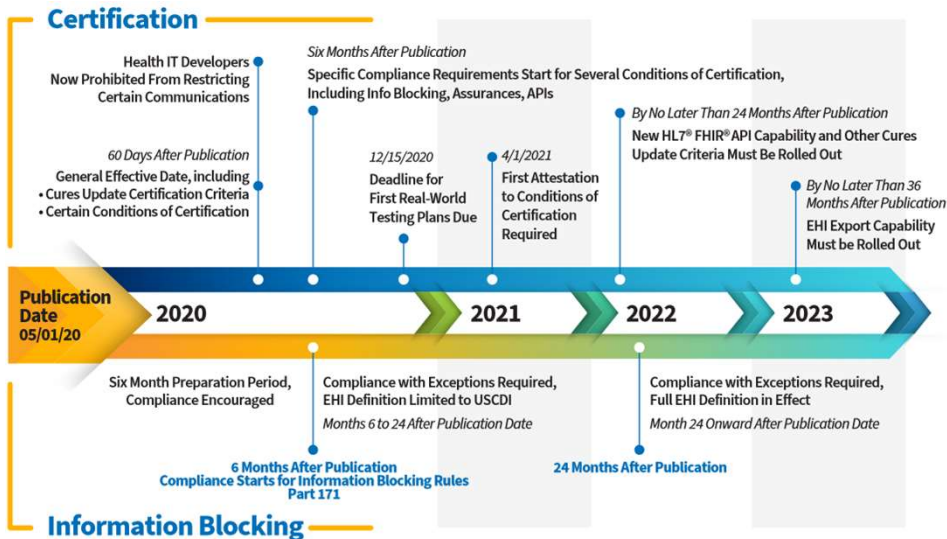
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# ONC Final Rule



## Highlighted Regulatory Dates



## Enforcement Discretion

Due to the COVID-19 public health emergency, ONC has announced its enforcement discretion to allow **an additional 3 months** before it will enforce compliance with **certain** provisions of the rule.

A full table of impacted provisions is here:

[https://www.healthit.gov/curer/sites/default/files/curer/2020-04/Enforcement\\_Discretion.pdf](https://www.healthit.gov/curer/sites/default/files/curer/2020-04/Enforcement_Discretion.pdf)

## Information Blocking

## What is Information Blocking?

A **practice by an actor that**, except as required by law or specified by the Secretary as a reasonable and necessary activity, is **likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information (EHI)**.

**Actor** means Health Care **Providers**; Health IT **Developers** of Certified HIT; or Health Information Exchanges and/or Health Information Networks (**HIEs/HINs**)

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## Knowledge Standard for Information Blocking

### Health Care Providers

- ...Knows that such practice is unreasonable and is likely to interfere with the access, exchange or use of EHI

### Health IT Developers and HINs/HIEs

- ...Knows, or should know, that such practice is likely to interfere with the access, exchange or use of EHI..

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## Definition of EHI

**EHI** means **electronic protected health information (ePHI)** to the extent that the ePHI is included in a **designated record set** (HIPAA-defined terms).

Does not include psychotherapy notes or info compiled in reasonable anticipation of civil or criminal action or proceeding.

*\*applicable whether the actor is a covered entity or not*

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## Exceptions

**Not Fulfilling Requests**  
§§171.201-205

- Preventing Harm
- Privacy
- Security
- Infeasibility
- HIT Performance

**Fulfilling Requests**  
§§171.301-303

- Content and Manner
- Fees
- Licensing

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## Preventing Harm Exception

- Actor must have a reasonable belief that practice will substantially reduce a risk of harm to a patient or another person;
- Practice must be no broader than necessary to substantially reduce the risk of harm; and
- Practice must satisfy at least one element of each of the following:
  - ✓ Practice is based on a type of risk;
  - ✓ Practice protects against a type of harm; and
  - ✓ Practice is implemented based on an organizational policy or a determination specific to the facts and circumstances

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## Privacy Exception

Practice must meet all of the requirements of at least one of the following sub-exceptions:

- Precondition imposed by law not satisfied;
- HIT developer of certified HIT not covered by HIPAA;
- Denial of an individual's request consistent with HIPAA Privacy Rule [45 CFR 164.524(a)(1) and (2)]; **or**
- Respecting an individual's request not to share information

ONC intends this exception to operate consistently with HIPAA Privacy Rule but notes that the information blocking rules may require actors to provide access, exchange, or use of EHI in situations where HIPAA does not.

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## Security Exception

- Practice must be directly related to safeguarding confidentiality, integrity, and availability of EHI;
- Practice must be tailored to the specific security risk being addressed; **and**
- Practice must be implemented in a consistent and non-discriminatory manner.

### Organizational Security Policies:

- ✓ Must be in writing;
- ✓ Have been prepared on the basis of, and be directly responsive to, security risks identified and assessed by or on behalf of the actor;
- ✓ Align with one or more applicable consensus-based standards or best practice guidance; **and**
- ✓ Provide objective timeframes and other parameters for identify, responding to, and addressing security incidents.

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## Infeasibility Exception

Practice must meet all of the requirements of at least one of the following conditions:

- Uncontrollable events;
- Segmentation; **or**
- Infeasible under the circumstances

### Timely Response Requirement

Actor must provide requestor in writing, **within 10 business days** of receipt of the request, the reason(s) why the request is infeasible

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## HIT Performance Exception

Practice must meet all of the requirements of at least one of the following conditions:

- Maintenance and improvements to HIT; or
- Assured level of performance; or
- Practices that prevent harm/ security related practices

## Content and Manner Exception

It will not be information blocking for an actor to limit the content of the response to a request to access, exchange or use EHI or the manner in which it fulfills a request if certain conditions are met.

Conditions for Content Condition and Manner Condition must be met.

## Complaint Process

- The Cures Act directs the National Coordinator to implement a standardized process for the public to submit reports on claims of information blocking.
- ONC will **implement and evolve** the complaint process. Information on how to file complaints is available at [www.healthit.gov/healthit-feedback](http://www.healthit.gov/healthit-feedback).

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## Penalties

- 21<sup>st</sup> Century Cures Act:
  - Civil Monetary Penalties (CMPs) up to \$1M per violation of info blocking rules
  - **Excluded** health care providers from being subject to CMPs
- OIG issued a proposed rule – new CMP authorities for info blocking enforcement (comments due June 23, 2020)
  - Proposes to delay penalty enforcement until 60 days after rule is finalized to allow time for compliance
- ONC will consider “appropriate disincentives” for providers in future rulemaking

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## **Compliance Timeline: Information Blocking**

Actors do not have to comply with the information blocking provision until 6 months after publication of the final rule. (November 1, 2020)

Enforcement of information blocking civil monetary penalties will not begin until the final OIG CMP rule is published.

## **Updating 2015 Edition Certification Criteria**

## Updating 2015 Edition Certification Criteria

### ➤ Technical Standards and Implementation Specifications:

- United States Core Data for Interoperability (USCDI) replaces the Common Clinical Data Set (CCDS)
- CMS standards replace HL7 standards for the “reporting eCQM data to CMS” criterion
- Adopt the FHIR US Core Implementation Guide STU 3 Release 3.1.0 (had proposed the Argonaut Implementation Guides)

### ➤ Revised and New 2015 Edition Criteria

- 11 areas including adding USCDI standard as the definitional framework, adding a new “EHI Export” criterion (replacing the “Data Export Criterion”), and a new API standard (replacing the “API Criterion”)

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## Revised and New 2015 Edition Criteria

New	Revised	Removed
<ul style="list-style-type: none"><li>• <b>EHI Export</b></li><li>• <b>Standardized API for Patient and Population Services</b></li><li>• Privacy and Attestation Criteria</li></ul>	<ul style="list-style-type: none"><li>• eRX (align with CMS)</li><li>• Clinical Quality Measurement (to align with CMS)</li><li>• Interoperability (USCDI, C-CDA Companion Guide)</li><li>• Security Tags &amp; Consent Management Criteria</li></ul>	<ul style="list-style-type: none"><li>• API (replaced)</li><li>• Data Export (replaced)</li></ul>

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## US Core Data for Interoperability (USCDI) Standard

**Timeline:** Developers need to update certified health IT to support USCDI (and all certification criteria affected by the switch to USCDI) by **May 2, 2022**

**Annual Update Schedule:** ONC will establish a “predictable, transparent, and collaborative” process to expand the USCDI

### Inclusion of New Required Data Classes/Elements:

- Provenance
- Clinical Notes
- Pediatric Vital Signs
- Address, Email & Phone Number

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## EHI Export Criterion

*EHI same as defined for information blocking*

### General Requirements:

- Capabilities for **both**:
  - ✓ **single patient EHI export** for patient access
  - ✓ **patient population EHI export** for transitioning health IT systems
- Export file must be **both**:
  - ✓ **Electronic and computable** format
  - ✓ Include a **publicly accessible hyperlink** of format

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# API Standards for Patient and Population Services

## Types of API-enabled services:

- 1) Services for a **single patient's** data
- 2) Services for **multiple patients'** data (aka population services)

## Some technical standards and requirements include:

- Health IT developers must support standardized APIs for **both types** of services
- Limited to **API-enabled "read" services** using HL7 FHIR Release 4 standard
- Search support to be able to respond to search requests for a single patient's data
- Demonstrate capability to establish a secure and trusted connection with an app that requests data
- Requirements for authentication and authorization

*Broadly:* Standards and requirements for implementation specifications intended to support development of third-party apps

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# Conditions and Maintenance of Certification

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## Implementation

Initial (**conditions**) and ongoing (**maintenance**) requirements for health IT developers and their certified health IT modules under ONC Health IT Certification Program

Applicability of requirements:

- *Information Blocking and Assurances*: developer responsible for ensuring that **ALL** of its health IT and related actions and behavior do not constitute info blocking
- *All Other Requirements*: developer responsible **only** for actions and behavior with **respect to certified health IT**

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## Provisions (45 CFR §§ 170.400-170.406)

- **Information Blocking** – compliance November 2, 2020
- **Assurances** – compliance varies; most time for assurances related to EHI Export Rollout (May 1, 2020 – May 2, 2023)
- **Communications** – compliance May 1, 2020, annual notice if contracts contain provisions contravening CoC beginning in CY 2020
- **APIs** – current API criteria: November 2, 2020; new Standardized API functionality: May 2, 2022
- **Real World Testing** – initial plan: December 15, 2020; initial results: March 15, 2022
- **Attestations** – first attestation window April 1-30, 2021 (covers May 1, 2020-March 31, 2021)
- **EHR Reporting Criteria Submission** – *forthcoming* (not included in rule)

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## Highlighted Provision - Communications

**Bars a health IT developer from prohibiting or restricting certain protected communications with narrow exceptions**

Communication as “any communication, irrespective of the form or medium and includes visual communications, such as screenshots and video”

- Note: Narrow exception allows developer limits on screenshots and video:
  - User cannot alter (except to resize or annotate);
  - User must only share with relevant number needed to communicate about the health IT; and
  - Video communications only where matter cannot be conveyed by screenshot or other means

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## Highlighted Provision - APIs

**A Certified API Developer must publish APIs and allow health information from APIs to be accessed, exchanged, and used without special effort using APIs, including providing access to all elements of a patient’s electronic health record to the extent permissible under applicable privacy laws.**

### **Additional Conditions:**

- Transparency Conditions
- Fees Conditions
  - Permitted fees
  - Prohibited fees
- Openness and Pro-Competitive Conditions

### **Key Terms**

*Certified API Developer:* a health IT developer that creates the ‘certified API technology’

*API User:* a person or entity that creates or uses software applications that interact with the ‘certified API technology’ developed by a ‘Certified API Developer’ and deployed by an ‘API Information Source’

*API Information Source:* an organization that deploys ‘certified API technology’ created by a ‘Certified API Developer’

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# Compliance & Enforcement

## Compliance

- Maintenance requirements are the preliminary baseline evidence used to measure whether a condition is being met
- Examine whether the certified health IT meets the full scope of the certification criteria rather than a subset of functions against which it was tested

## Enforcement

- Bans and Terminations
- ONC and OIG overlap (info blocking and attestations)
- Self Developers **are** subject to Conditions and Maintenance requirements

# Other Topics in the ONC Rule

## Health IT Across the Care Continuum

- Pediatric Setting
  - Recommendations for a *Voluntary* Certification of Pediatric Health IT
  - Certification Criteria and Standards for Pediatric Health IT
- Opioid Use Disorder Prevention and Treatment RFI
  - Received over 100 comments and input from the HITAC and states

## CMS Final Rule

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## New Conditions of Participation (CoPs) for Hospitals and CAHs

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## Electronic ADT Event Notifications

Hospitals, including psychiatric hospitals and CAHs, must send electronic patient event notifications of a patient's admission, discharge, or transfer to another healthcare facility or to another community provider or practitioner.

Includes:

- Patient registration in the emergency department (ED);
- Admission as an inpatient (regardless of source of admission);
- Discharge or transfer from ED; and
- Discharge or transfer from inpatient services.

**Timeline for Compliance: May 2, 2021**

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## ADT Event Notification Standards

### Notification must include:

- Patient name;
- Treating practitioner name; and
- Name of the sending hospital

### Transmission of notification may be made:

- Directly; or
- Through an intermediary that facilitates exchange of health information (e.g., HIE)

## Notification to Whom?

Hospitals must make a reasonable effort to ensure notification to specified providers who need to receive notification of patient's status for treatment, care coordination, or quality improvement purposes.

Providers include:

- Applicable PAC providers with an established relationship immediately before admission or to which the patient is being transferred or referred at discharge; **and**
- Patient's established primary care practitioner/practice group or entity; or
- Other established practitioner/group/entity identified by the patient as primarily responsible for the patient's care.

**If a patient does not identify a primary care practitioner and/or no applicable PAC provider, hospital is not expected to provide such a notification.**

## Public Reporting: Information Blocking and Provider Digital Contact Information

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### Information Blocking

CMS will begin to publicly report clinicians, hospitals, and CAHs that may be information blocking based on their respective attestations to Medicare Promoting Interoperability Program requirements

**Timeline:** late 2020 (using 2019 performance data)

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## Digital Contact Information

CMS will begin to publicly report providers who do not list or update their digital contact information in the National Plan and Provider Enumeration System (NPPES)

**Timeline:** late 2020

### Digital contact information:

- Direct Address and/or
- FHIR API endpoint

## Patient Access Through APIs

## Patient Access API

CMS-regulated payers are required to implement and maintain a secure, standards-based (HL7 FHIR Release 4.0.1) API that allows patients to easily access their claims and encounter information, including cost, as well as a defined sub-set of their clinical information through third-party applications of their choice.

**Implementation timeline:** January 1, 2021 (plan years beginning on or after)

### CMS-Regulated Payers

MA organizations, Medicaid Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP FFS programs, CHIP managed care entities, and QHP issuers on the Federally-Facilitated Exchanges (FfEs)

**Excluding:** Issuers offering only stand-alone dental plans (SADPs) and QHP issuers offering coverage in the Federally-facilitated Small Business Health Options Program (FF-SHOP)

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## Provider Directory API

CMS-regulated payers [specifically MA organizations, Medicaid FFS programs, Medicaid managed care plans, CHIP FFS programs, and CHIP managed care entities\*] are required to make provider directory information publicly available via a standards-based API.

**Implementation timeline:** January 1, 2021

*\*QHP issuers on the FfEs are already required to make provider directory info available in a machine-readable format.*

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## Health Information Exchange and Care Coordination Across Payers

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### Payer-to-Payer Data Exchange

CMS-regulated payers are required to exchange certain patient clinical data (specifically the U.S. Core Data for Interoperability (USCDI) version 1 data set) at the patient's request, allowing the patient to take their information with them as they move from payer to payer over time to help create a cumulative health record with their current payer.

**Implementation Timeline:** January 1, 2022 (plan years beginning on or after)

#### CMS-Regulated Payers

MA organizations, Medicaid Fee-for-Service (FFS) programs, Medicaid managed care plans, CHIP managed care entities, and QHP issuers on the Federally-Facilitated Exchanges (FfEs)

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# Q & A

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# Resources

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## ONC and CMS Resources

ONC – Cures Act Final Rule Website

<https://www.healthit.gov/curesrule/>

CMS – Interoperability and Patient Access final rule

<https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>

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## Summary 2015 Edition Cures Update (Table 1)

Certification Criterion	Reference	Change Type	Change Timing	Impact CMS PI Programs
Problems List	§ 170.315(a)(6)	Removed	30 Jun 2020	Removed from 2015 Edition Base EHR
Medication List	§ 170.315(a)(7)	Removed	30 Jun 2020	Removed from 2015 Edition Base EHR
Medication Allergy List	§ 170.315(a)(7)	Removed	30 Jun 2020	Removed from 2015 Edition Based EHR
Drug Formulary and Preferred Drug List Checks	§ 170.315(a)(10)	Time-limited	ONC-ACBs may certify until 1 Jan 2022	e-Rx and PDMP Query measures operational for Medicaid until 2022
Smoking status	§ 170.315(a)(11)	Removed	30 Jun 2020	Removed from 2015 Edition Based EHR
Patient-specific Education Resource	§ 170.315(a)(13)	Time-limited	ONC-ACBs may certify until 1 Jan 2022	Operational for Medicaid until 2022
Transitions of Care	§ 170.315(b)(1)	Revised	Update to USCDI or C-CDA companion IG by 2 May 2022	Measures: Support Electronic Referral Loops Send/ Receive and Incorporate

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## Summary 2015 Edition Cures Update (Table 1), continued

Clinical information reconciliation and incorporation	§ 170.315(b)(2)	Revised	Update to USCDI or C-CDA companion IG by 2 May 2022	Measure: Support Electronic Referral Loops Receive and Incorporate
Electronic Prescribing	§ 170.315(b)(3)	Revised	Update standard by 2 May 2022	Measure: e-Prescribing
CCDS Summary – Create	§ 170.315(b)(4)	Removed	30 June 2020	No impact described
CCDS Summary – Receive	§ 170.315(b)(5)	Removed	30 June 2020	No impact described
Data Export	§ 170.315(b)(6)	Time-limited	ONC-ACBs may certify until 2 May 2022	Removed from Base EHR 30 Jun 2020
Security tags – summary of care – send	§ 170.315(b)(7)	Revised	Document, section, and entry (data element) level; or Document level until 2 May 2022	No impact described
Security tags – summary of care - receive	§ 170.315(b)(8)	Revised	Document, section, and entry (data element) level; or Document level until 2 May 2022	No impact described
Care plan	§ 170.315(b)(9)	Revised	Update to C-CDA companion guide by 2 May 2022	No impact described

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## Summary 2015 Edition Cures Update (Table 1), continued

EHI Export	§ 170.315(b)(10)	New	Update by 2 May 2023	No impact described
Clinical Quality Measures – report	§ 170.315(c)(3)	Revised	30 Jun 2020	Measures: eCQMs
Auditable events and tamper-resistance	§ 170.315(d)(2)	Revised	Update to new ASTM standard by 2 May 2022	No impact described
Audit report(s)	§ 170.315(d)(3)	Revised	Update to new ASTM standard by 2 May 2022	No impact described
Auditing actions on health information	§ 170.315(d)(10)	Revised	Update to new ASTM standard by 2 May 2022	No impact described
Encrypt authentication credentials	§ 170.315(d)(12)	New	30 Jun 2020 (new and updated certifications only)	No impact described
Multi-factor authentication (MFA)	§ 170.315(d)(13)	New	30 Jun 2020 (new and updated certifications only)	No impact described
View, Download, and Transmit to 3 <sup>rd</sup> Party	§ 170.315(e)(1)	Revised	Update to USCDI/C-CDA companion guide by 2 May 2022	Measure: Provide Patients Electronic Access to Their Health Information

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## Summary 2015 Edition Cures Update (Table 1), continued

Secure Messaging	§ 170.315(e)(2)	Time-limited	ONC-ACBs only permitted to issue certificates until 1 Jan 2022	Operational for Medicaid until 2022
Transmission to public health agencies – electronic case reporting	§ 170.315(f)(5)	Revised	Update to USCDI/C-CDA companion guide by 2 May 2022	Measure: Electronic Case Reporting
Consolidated CDA creation performance	§ 170.315(g)(6)	Revised	Update to USCDI/C-CDA companion guide by 2 May 2022	No impact described
Application Access – Data Category Request	§ 170.315(g)(8)	Time-limited	Available until 2 May 2022	Measure: Provide Patients Electronic Access to Their Health Information
Application Access – All Data Request	§ 170.315(g)(9)	Revised	Update to USCDI/C-CDA companion guide by 2 May 2022	Measure: Provide Patients Electronic Access to Their Health Information
Standardized API for patient and population services	§ 170.315(g)(10)	New	Update by 2 May 2022	Added to 2015 Edition Based EHR definition

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