On May 1, the Centers for Medicare and Medicaid Services (CMS) and the Office of the National Coordinator for Information Technology (ONC) published companion final rules in the Federal Register that implement provisions in the 21st Century Cures Act related to interoperability, electronic health records (EHR) certification and information blocking. An April 21, a few weeks prior to the formal publication of the two rules, the agencies announced that they will delay enforcement of certain provisions of the final rules beyond the compliance dates established in the rules in recognition of the health care industry’s current focus on the ongoing COVID-19 public health emergency.

Among the many provisions of these comprehensive and complex rules are new requirements that the health information that must be made available and shared with patients and providers in EHRs include claims and billing information. While the rule does not explicitly state that price information must be shared in the EHR, it could be included to the extent it is a part of claims or other billing records. In addition, the CMS rule expands the Medicare and Medicaid Conditions of Participation (CoPs) to require electronic notification by hospitals to patients’ primary care providers upon admission, transfer or discharge.

The CMS rule is intended to advance interoperability and improve access to, and the quality of, information that patients need to make informed health care decisions, including data about prices and outcomes, without increasing the reporting burden on payers or providers. CMS states that its intent in promoting interoperability is to help advance coordinated care, identify population health trends, improve outcomes and control costs.

The ONC rule implements 21st Century Cures Act provisions related to the enhancement of health information technology (HIT) certification, including voluntary certification of pediatric HIT, prevention of information blocking, implementation of other interoperability initiatives, and improving patient electronic access to their health information. It also includes the provisions that could expand patient’s electronic access to health care pricing information.

CHA submitted comment letters to CMS and the ONC on their respective proposed rules that focused on aspects of the rules with implications for children’s health care including issues of safety, security and confidentiality considerations that are unique to pediatrics.

- **CHA comments to CMS:** The [CHA letter to CMS](https://www.childrenshospitals.org) highlighted our opposition to the proposed expansion of the Medicare and Medicaid CoPs to require all hospitals to electronically notify all of a patient’s providers when the patient is admitted, discharged or transferred. The letter also included recommendations for changes to the proposed requirement that providers give patients’ access to their health information through

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1 CHA also joined with other hospital groups on a [letter to HHS](https://www.childrenshospitals.org) to express concern with the use of the CoPs as the mechanism to advance health information exchange.
open Application Programming Interfaces (APIs) to better advance the health care needs and outcome goals of child patients, families and caregivers and appropriately protect the pediatric patients’ privacy.

- **Final CMS rule:** CMS is finalizing the expanded CoP with some revisions to limit the type of information that needs to be shared and the providers with whom it is shared in the notifications. The agency acknowledged, in the preamble to the rule, concerns regarding pediatric and adolescent privacy, but did not include any specific measures in the final rule.

- **CHA comments to ONC:** The CHA letter to the ONC included our recommendations related to the types of EHR data that should be collected for pediatric care; refinements to proposed voluntary pediatric EHR certification requirements and related testing of EHR technology; and concerns regarding the proposed inclusion of prices in health information exchange requirements.
  - **Final ONC rule**
    - EHR certification—The ONC adopted its proposal to include Pediatric Vital Signs in certified EHR, which we supported. The agency did not adopt our other pediatric-specific recommendations to refine the pediatric data elements in the EHR and did not adopt our recommendations for formally requiring pediatric certification of EHRs for use in pediatric settings or for their testing in pediatric settings. However, CMS did clarify that all EHR testing should be done in the type of clinical setting in which it will be used.
    - Prices in definition of EHI—The proposed ONC rule included a request for information on the parameters and implications of including price information within the scope of the definition of the EHI that would be subject to the information blocking prohibition, but the final rule leaves some ambiguity in this regard. Instead, the rule includes claims and other billing records as EHI that must be shared per the information blocking prohibition and notes in the preamble that pricing information would also be subject to those provisions to the extent it is a part of claims and billing records. However, the agency delayed the full implementation of the information blocking provision until May 1, 2022.

Key provisions of the final rules with implications for children’s health care and children’s hospitals, include:

- **CMS rule**
  - Requires all health plans regulated by CMS to provide enrollees access to their electronic health information (EHI) through open applications (apps) available on smart phones, tablets, etc.
  - Establishes a new Medicare and Medicaid CoP that would require hospitals, including children’s hospitals, to send automated electronic patient event notifications to a patient’s primary care provider when the patient is admitted, discharged or transferred.

- **ONC rule**
  - Expands the data that must be provided through certified EHRs to include Pediatric Vital Signs.
  - The identification of pediatric HIT elements for voluntary adoption.
  - Implements the prohibition on certified HIT developer or health care provider interference with the exchange or use of EHI with patients, plans and other providers (information blocking). The rule defines EHI to include information on payment for services, which could include price information to the extent that it is a part of claims and bills.

**DETAILED SUMMARY OF CMS FINAL RULE**

The CMS rule applies to Medicaid and CHIP fee-for-service programs, Medicaid and CHIP managed care plans, Medicare Advantage and Qualified Health Plans in the federally facilitated Exchanges. It does not apply to other
commercial plans in the large or small group markets or in the state-based Exchanges, though those plans are encouraged to adopt the policies delineated in the rule.

Patient Access Through Application Programming Interfaces (APIs)
The final rule requires all health coverage and plans to implement two types of openly published APIs that permit third-party software applications to retrieve enrollees’ plan information, including clinical and payment information as well as information about plan provider networks. The open APIs are intended to make it possible for enrollees to access their own EHI and other information relevant to their health and health care (as allowed under HIPAA) through common technologies (e.g., smart phones, tablets) and apps of their choice, beginning July 1, 2021.²

- Patient Access API—must provide, at a minimum, enrollee identifiers; dates of service; adjudicated claims (including cost); encounters with capitated providers; provider remittances; enrollee cost-sharing; and clinical data (including lab results if covered under the plan).
  - Data must be made available no later than one business day after a claim is adjudicated for encounter data is received by the payer.
  - Clinical data must follow standards delineated in the new U.S. Core Data for Interoperability (USCDI).³

- Provider Directory API—must provide information about in-network providers, which includes, at a minimum provider names, addresses, phone numbers and specialties. Data must be publicly available within 30 days of a payer receiving provider directory information or updates.

- APIs are required to use the Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (FHIR) Release 4.0.1 as the foundational standard to support data exchange.

Care Coordination Across Payers: Transactions to Communicate Between Plans
The final rule requires payers to forward USCDI data on an enrollee to other payers that are designated by an enrollee (or authorized representative) at any time during coverage or up to five years after coverage ends.

- Effective Jan. 1, 2022,⁴ and applies to all data related to services received on or after Jan. 1, 2016.

Disclosure of Providers Engaged in Information Blocking
CMS is required to publicly display—via the Physician Compare website—the names of clinicians that fail to attest, as part of the CMS Merit-Based Incentive Program, that they have not engaged in activities that could be considered information blocking.⁵ In addition, the names of hospitals that participate in the Promoting Interoperability Program and do not submit similar attestations will be posted on a public web site. Providers must comply with attestation requirements beginning with the respective 2019 reporting periods. This provision goes into effect late 2020. Specifically, providers must attest that they:

- Did not knowingly and willfully take action to limit or restrict the compatibility or interoperability of certified HIT.

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² This is the new implementation date per the April 21 extended deadline announcement.
³ The USCDI replaces the Common Clinical Data Set that is currently required in certified HIT. The ONC final rule delineates the specific components of the USCDI, which includes, among other items, clinical notes, vital signs (including pediatric), patient goals, laboratory tests, medications, patient demographics, immunizations and procedures.
⁴ This is the new implementation date per the April 21 extended deadline announcement.
⁵ The Public Health Service Act was amended by the CURES Act to define information blocking as practices that interfere with, prevent or materially discourage access, exchange or use of electronic health information. More specific information about information blocking is included in the summary of the ONC final rule.
• Implemented technologies and other practices to ensure that their certified HIT is connect and compliant with the law.
• Responded in good faith and in a timely manner to requests to retrieve or exchange EHI.

Provider Digital Contact Information
The final rule requires health care providers and facilities to add digital contact information to the National Plan and Provider Enumeration System, which supplies and maintains National Provider Identifier numbers, beginning in the second half of 2020. This requirement is intended to enhance interoperability and information exchange by providing a resource where users can obtain information about how to securely transmit EHI to a provider.

Revisions to Conditions of Participation (CoPs) to Include Electronic Notification Standards For Health Care Providers
The Medicare and Medicaid CoPs are revised to require hospitals, including children’s hospitals, short-term acute care hospitals, long-term care hospitals, rehabilitation hospitals, psychiatric hospitals, cancer hospitals and critical access hospitals, to send automated electronic patient event notifications to another facility or provider when a patient is seen in the emergency department, admitted, discharged or transferred.

• Notifications must:
  o be sent when a patient registers in the emergency department or is admitted, and either immediately prior to, or at the time of, discharge or transfer.
  o be sent directly, or through an intermediary, to: post-acute care providers and suppliers, the patient’s established primary care practitioner and established primary care practice group, other practitioner or practice groups or entities identified by the patient as primarily responsible for their care.
  o include the patient’s name, the treating practitioner’s name and the sending institution’s name, at a minimum.

• To be in compliance, a hospital must demonstrate that:
  o it has processes and policies in place to identify patients’ primary care practitioners and incorporate that information into the patient event notification system.
  o it “has made a reasonable effort to ensure that” it has sent the requisite notification of the patients’ status for treatment, care coordination or quality improvement purposes to all applicable providers.

• Hospitals will not be penalized if:
  o they are not able to identify a patient’s primary care practitioner.
  o they do not utilize EHR systems or other electronic administrative systems that conform with the HL7 2.5.1 standard.7
  o the intended primary care recipient of an electronic notifications does not have the technological capability to receive the information.
  o a patient requests that the information not be shared with another provider.

• Hospitals must comply with HIPAA and related state and federal privacy laws when sharing information.
• Compliance will be determined through the Medicare and Medicaid survey and certification systems.

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6 The final rule does not include technical specification requirements regarding how the notifications are formatted or technological standards for the sharing of the information.
7 The content exchange standard in the 2015 Edition for exchanging EHI, which is being updated in this rule.
This requirement goes into effect on May 1, 2021.8

DETAILED SUMMARY OF ONC FINAL RULE

Updates and Modifications to HIT Requirements
The ONC final rule made several changes that affect the types of information an EHR must share and how the data should be structured and made available. First, the final rule replaces the Common Clinical Data Set (CCDS), which is currently used in the 2015 Edition Health IT Certification Criteria (2015 Edition)9, with the first version of the United States Core Data for Interoperability (USCDI v1) as the national standard for the information that EHRs must be able to share. Second, the rule introduces several new criteria, and revises and removes several existing criteria for HIT developers to meet certification requirements.

- Data Classes and Data Elements included in the USCDI v1
  The final rule adopts the following data elements of the USCDI as the “language” that must be used in EHRs. ONC intends to expand the USCDI over time and will establish a public website to solicit public comment on changes and additions, as well as a public comment period upon the release of any updates. For more information about the USCDI, visit the ONC website.
  - Allergies and Intolerance—Substance (Medication), Substance (Drug Class), and Reaction
  - Assessment and Plan of Treatment
  - Care Team Members
  - Clinical Notes (free text portion of clinical notes for interoperable exchange). Includes (for inpatient and outpatient services):
    - Consultation Note and Discharge Summary Note
    - History & Physical
    - Imaging, Laboratory Report, and Pathology Report Narratives
    - Procedure and Progress Notes
  - Goals, including patient goals
  - Health Concerns
  - Immunizations
  - Laboratory—Tests, Values/Results
  - Medications
  - Patient Demographics
    - First Name, Last Name, Previous Name, Middle Name (including middle initial), Suffix
    - Birth Sex, Date of Birth
    - Race, Ethnicity, Preferred Language
    - Current Address, Previous Address, Phone Number, Email Address
  - Problems
  - Procedures
    - Provenance—when and who created the data, including Author Time Stamp and Author Organization
  - Smoking Status
  - Unique Device Identifier(s) for a Patient's Implantable Device(s)
  - Vital Signs, which includes these pediatric-specific metrics:
    - BMI Percentile (2-20 years)
    - Weight-for-length Percentile (Birth - 36 months)

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8 This is the new implementation date per the April 21 extended deadline announcement.
9 Establishes the capabilities and related standards and implementation specifications that Certified EHR Technology (CEHRT) must meet under the Medicare and Medicaid Interoperability Program.
- Head Occipital-frontal Circumference Percentile (Birth - 36 months)

- **HIT Certification Criteria**
  The final rule updates the standards for EHRs that developers must meet to be certified under the HHS Medicare and Medicaid Promoting Interoperability Program. The standards allow for the storage and transfer of data in a structured format in the EHR.\(^{10}\) The following criteria changes may be relevant to children’s hospitals interoperability efforts.
  - **New certification criteria**
    - Criteria to advance interoperability and ease patients’ access to their EHI on their smartphones
      - EHI Export—Focuses on the ability to export EHI stored in and by certified HIT to support patient requests and health care providers who transition to another HIT system.
      - Standardized API for Patient and Population Services—Requires the use of the HL7® FHIR® Release 4 standard for services for which a single patient’s data is the focus, and services for which multiple patients’ data are the focus.
    - Criteria to require transparency attestations from developers
      - Encrypt Authentication Credentials
      - Multi-factor Authentication
  - **Revised certification criteria**
    Standards related to these existing criteria were revised:
    - ePrescribing
    - Adjustable Events and Tamper-Resistance
    - Security Tags — Summary of Care (send) and Security Tags — Summary of Care (receive)
    - Audit Report(s)
    - Auditing Actions on Health Information
    - Electronic clinical quality measures (CQMs) — Report

For more information on the changes to the certification criteria, see the [ONC website].(https://www.healthit.gov/topic/learn-aboutHITEHR/certification/certification-criteria)

**Pediatric HIT Certification Criteria**
The 21\textsuperscript{st} Century Cures Act requires ONC to establish a pediatric EHR certification program and the final rule takes a limited regulatory approach by not adopting care or practice-specific certification tracks or a specific voluntary pediatric program. Instead, the final rule identifies existing, new and revised criteria from the 2015 Edition that support pediatric care, align with the Children’s Model EHR Format\(^{11}\) and correspond to ten pediatric-focused broad recommendations (i.e., objectives) for pediatric EHRs that the ONC developed in consultation with stakeholders. The pediatric recommendations are:

- Use biometric-specific norms for growth curves and support growth charts for children
- Compute weight-based drug dosage
- Have the ability to document all guardians and caregivers
- Allow for segmented access to information
- Synchronize immunization histories with registries
- Allow age-and weight-specific single dose range checking

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\(^{10}\) The Medicaid Promoting Interoperability Program’s incentive payments to Medicaid providers end on Dec. 31, 2021.

\(^{11}\) [https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format](https://healthit.ahrq.gov/health-it-tools-and-resources/pediatric-resources/childrens-electronic-health-record-ehr-format)
The ONC notes that it plans to supplement the final rule’s identified EHR criteria that are pediatric-relevant with additional informational resources and subregulatory guidance on its pediatric HIT website. The following chart shows the voluntary pediatric-relevant criteria identified in the rule, their purpose and relationship to the 2015 Edition.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Purpose</th>
<th>Existing/New/Revised</th>
</tr>
</thead>
<tbody>
<tr>
<td>API functionality criteria</td>
<td>Addresses parental access/multiple portal challenges by allowing the aggregation of information from multiple sources into a mobile application and to be accessed, exchanges and used form APIs without special effort</td>
<td>Existing/New/Revised</td>
</tr>
<tr>
<td>Care plan criterion</td>
<td>Facilitates documentation of EHI in a structured format to improve care coordination</td>
<td>Existing</td>
</tr>
<tr>
<td>Clinical decision support</td>
<td>Enables interventions based on the capture of biometric data</td>
<td>Existing</td>
</tr>
<tr>
<td>Data segmentation for privacy</td>
<td>Provides the ability to create, receive and view a summary record that can be tagged as “restricted.” Also adds a FHIR criteria, both of which support a granular approach to privacy.</td>
<td>Existing/New/Revised</td>
</tr>
<tr>
<td>Demographics criterion</td>
<td>Allows for improved patient matching and allows for the capture of values and value sets relevant to pediatrics</td>
<td>Existing</td>
</tr>
<tr>
<td>Electronic Prescribing criterion</td>
<td>Includes an option that allows for the exchange of weight-based dosing calculations and other safe prescribing practices for children. New criteria support improved patient safety and prescription accuracy, workflow efficiencies and functionality related to pediatric prescribing practices</td>
<td>Existing/New/Revised</td>
</tr>
<tr>
<td>Family health history criterion</td>
<td>Captures familial conditions that are clinically relevant to the care of children</td>
<td>Existing</td>
</tr>
<tr>
<td>Patient health information capture criterion</td>
<td>Supports providers’ ability to accept health information from a patient or authorized representative. Allows for the documentation of decision-making authority of a patient representative</td>
<td>Existing</td>
</tr>
<tr>
<td>Social, psychological, and behavioral data criterion</td>
<td>Supports integration of behavioral health data into the child’s record across the care continuum by allowing user to record, change and access patient data</td>
<td>Existing</td>
</tr>
<tr>
<td>Transitions of care criterion</td>
<td>Supports structured transition of care summaries as children transfer between providers and different levels of care</td>
<td>Existing</td>
</tr>
</tbody>
</table>
Criteria | Purpose | Existing/New/Revised
---|---|---
Transmission to immunization registries criterion | Allows for linkages with registries to support pediatric health care, including up-to-date information about a patient’s immunization history | Existing
View, download, and transmit to 3rd part criterion | Allows patients to view, download and transmit their health information to a 3rd party. | Existing
USCDI-based criteria | Enables the inclusion of pediatric vital sign data elements | New

**Conditions and Maintenance of Certification**

The final rule implements 21st Century Cures Act requirements to establish conditions and maintenance of certification requirements for HIT developers that allow certification to be revoked for bad behavior. If an EHR vendor were to lose certification, providers and hospitals participating in the Medicare and Medicaid Promoting Interoperability Program that use that particular software could be hit with penalties. Conditions of certification with relevance to children’s hospitals’ use of certified HIT include the following:

- HIT developers are prohibited from:
  - taking any actions considered information blocking. (See below for a summary of the final rule’s information blocking provisions.)
  - imposing any restrictions on certain aspects of HIT performance and related business practices.

- HIT developers are required to:
  - provide assurances to the secretary that they are not taking any actions to inhibit the appropriate exchange, access or use of EHI.
  - successfully test on an annual basis the use of HIT for interoperability in the type(s) of settings in which it will be marketed. In response to comments from CHA and allied organizations, the final rule’s preamble clarifies that developers are expected to test pediatric HIT in pediatric settings and in real-life situations.

The final rule also establishes specific [API Conditions of Certification](#) that address the practices HIT developers must engage in to minimize any “special effort” to access, exchange, and use all data elements of a patient’s EHI via certified API technology.

**Prohibition on Information Blocking**

As required under the 21st Century Cures Act, the final rule prohibits any certified HIT developer, health care provider or other “actor” from taking any action that is likely to interfere with access, exchange or use of EHI. The rule defines the specific EHI that will be protected from information blocking, defines the “actors” subject to the information blocking prohibition, delineates the specific types of actions that are considered to be information blocking, and finalizes eight exceptions to what constitutes information blocking. The information blocking rules are generally effective Nov. 1, 2020, but apply to a limited set of EHI. Full implementation is set for May 2022 (see below).

- **Definition of EHI**
  - The final rule’s definition of EHI aligns with the definition of electronic protected health information (E PHI) under HIPAA regulations. The E PHI will be protected to the extent that information is part of
a patient’s EHR or another designated record under HIPAA, regardless of whether the record is used or maintained by or for a HIPAA-covered entity.

- The protected information includes the following, with the exception of psychotherapy notes and information that is collected for use in a criminal or administrative proceeding.
  - Patients’ medical and billing records.
  - Enrollment, payment, claims adjudication, and case/medical management records maintained by a health plan. The final rule does not explicitly include providers’ price information or payment rates in the definition of EHI. However, that information would be included to the extent it is included in claims or other billing records.
  - Records used by a covered entity to make decisions about an individual.

- **NOTE:** the final rule delays for 24 months (until May 2022) the full implementation of the EHI definition, including information related to claims, billing or payment information, that is subject to the information blocking prohibition.
  - During that delayed timeframe, the information that is subject to the information blocking prohibition is limited to the data elements in the USCDI.

- **“Actors” subject to the information blocking prohibition.**
  The final rule specifies the entities that must comply with the prohibition on information blocking.
  - Health care providers, as defined under the Public Health Services Act, including hospitals, ambulatory surgical centers, group practices, physicians, laboratories, nursing homes, therapists, and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the secretary.
  - Health Information Networks or Health Information Exchanges, which are defined as entities that enable, facilitate or control the movement of information related to treatment, payment and health care operations (as defined under HIPAA) between or among two or more unaffiliated entities.
  - Certified HIT developer, which is defined as an individual or entity, other than a health care provider, that self-develops HIT for its own use, develops or offers HIT and has at least one module certified by the ONC.

- **Practices that are information blocking**
  The final rule identifies five categories of activities that are considered information blocking and are prohibited. The practices are those that are likely to interfere with access to, exchange of or use of EHI, which the actor knows are unreasonable and will discourage or interfere with EHI access or use. The five categories are:
  - Restrictions on access, exchange or use through contract terms, etc.
    - For example a HIPAA Business Associate Agreement cannot allow access to EHI by certain providers for treatment purposes while limiting access for the same purpose by the patient’s other providers.
  - Limiting or restricting HIT interoperability.
    - For example, developers or providers cannot restrict the public availability of access points to an API.
  - Impeding innovation in the access, exchange or use of HIT-enabled health care delivery, including third party apps.
  - Opportunistic pricing practices that artificially increase costs to access EHI.

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12 A “business associate” is a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. Functions and activities include: claims processing or administration; data analysis, processing or administration; utilization review; quality assurance; billing; benefit management; practice management; and repricing. Services can be legal; actuarial; accounting; consulting; data aggregation; management; administrative; accreditation; and financial.
Non-standard implementation practices, such as using proprietary technical formats when a generally acceptable one is available.

- **Information blocking exceptions**
  
  **ONC finalized eight exceptions** to the prohibition on information blocking that allows for “reasonable and necessary” practices that would not be considered to be information blocking. The exceptions are broken into two categories:
  
  1. Exceptions that involve not fulfilling requests to access, exchange, or use EHI.
     - Preventing Harm—Recognizes that the public interest in protecting patients against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of EHI.
     - Privacy exception—Allows an actor to not fulfill a request to access, exchange, or use EHI in order to protect an individual’s privacy and when fulfilling the request would be in violation of privacy laws.
     - Security Exception—Allows actors to implement reasonable and necessary security measures and interfere with the access, exchange, or use of EHI in order to protect the security of the EHI.
     - Feasibility Exception—Recognizes that legitimate practical, technological, legal or other challenges may limit an actor’s ability to comply with requests for access, exchange, or use of EHI.
     - Health IT Performance Exception—Recognizes that for HIT to perform properly and efficiently, it must be maintained, and in some instances improved, which may require that it be taken offline temporarily.
  
  2. Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI
     - Content and Manner Exception—Identifies the information (i.e., scope of EHI) that an actor must provide in response to a request and the manner in which it must be provided by identifying permissible limitations on what is provided and how it is provided.
     - Fees Exception—Allows an actor to charge reasonable fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using EHI, as long as the fees are not charged in a discriminatory manner.
     - Licensing—Allows an API provider to license interoperability elements and charge reasonable royalties for EHI to be accessed, exchanged, or used, provided the licenses are non-discriminatory.

- **Information blocking prohibition enforcement and penalties**
  
  The final rule gives the HHS Office of the Inspector General (OIG) investigatory and enforcement authority over information blocking. The OIG has issued a companion proposed rule that delineates its proposed investigation process of suspected information blocking and the enforcement of civil monetary penalties. The proposed rule allows the OIG to impose a civil monetary penalty of up to $1 million "per violation" on HIT developers, health information networks or health information exchanges that are found to have engaged in information blocking. Appropriate disincentives for providers who may engage in information blocking will be established by the secretary in future rulemaking. According to the proposed rule, the OIG will consider, when determining whether a provider committed information blocking, whether, an HIT developer or other entity offering HIT to the provider failed to ensure that the technology meets federal certification requirements.