Department of Health and Human Services; Office of the Secretary

45 CFR Parts 170 and 171
RIN 0955-AA01

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

SUMMARY: This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information. The proposed rule would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.

Submit comments: *Electronically.* You may submit electronic comments through https://www.regulations.gov/document?D=HHS-ONC-2019-0002-0001

Comments due to ONC: June 3 2019, at 11:59 PM ET

Overall Comment

Text:

N/A

Comment:

Please consider including a list of acronyms, definitions and hyperlinks when applicable in the final rule as its own section for easy reference while reading the guide.

Acronym Examples

- CHIP: Children's Health Insurance Program
- FFE: Children's Health Insurance Program
- MA: Medicare Advantage
- MCO: managed care organization
- MLR: Medical Loss Ratio
- PAHPs: prepaid ambulance health plan
- PHSA: Public Health Service Act
- PIHPs: prepaid inpatient health plans
- QHP: qualified health plans
- QIA: Quality improvement activity
- UPI: Unique Patient Identifier

We recommend EHI / Electronic Health Information and EPHI / Electronic Protected Health Information have clear and succinct definitions for reference by both the healthcare and technical communities.

Overall Comment

Text:

N/A

Comment:

As you finalize this ruling, you may want to consider the impact of laboratory results being shared with the patient from different sources due to potential for varying vocabularies (such as SNOMED, LOINC, RxNORM), standards formats, and result statuses as potential impacts to the data. Information sent to payers are not subject to the same regulatory requirements that exist between laboratories and the ordering/attending provider. Potential disparities in how the data is displayed and stored in these systems may further construe the information shared with the patient. We are concerned this may cause a patient safety risk.

We recommend that patient laboratory results be rendered to the patient from their ordering/attending provider as their trusted primary health care provider as data sent to the plan is traditionally for payment and not patient care.

Overall Comment

Text:

N/A

Comment:

The Trusted Exchange Framework and Common Agreement (TEFCA) is also out for public comment with a deadline of June 17, 2019. There may be some overlap in comments between the ONC Health IT Certification Program and TEFCA responses; therefore, we ask the agency to consider both when creating this final rule.

(Page 7441) ii. Address and Phone Number

Text:

The USCDI v1 includes new data elements for ''address'' and ''phone number.'' The inclusion of ''address'' (to represent the postal location for the patient) and ''phone number'' (to represent the patient's telephone number) would improve the comprehensiveness of health information for patient care. The inclusion of these data elements is also consistent with the list of patient matching data elements already specified in the 2015 Edition ''transitions of care'' certification criterion (§ 170.315(b)(1)(iii)(G)), which supports the exchange of patient health information between providers of patient care.

Comment:

Please clarify if the expected address and phone number formats to be supported are the same as defined in the 2015 Edition transitions of care, which is a C-CDA (Consolidated Clinical Document Architecture) based standard. We prefer uniform formats for the USCDI. Can you clarify whether multiple addresses and phones numbers will be supported and recognized by type (such as: Work, Home, Land Line, and Mobile)?

For secondary data recipients, e.g. a referral or specialized laboratory, the address and phone number may not be provided to the lab, thus is not available for patient matching or other purposes. Obtaining that information is burdensome and costly. It would be available from the provider's EHR system.

If different from the format for other standards ONC has required for certification in the past (for example C-CDA or V2 LRI[1]) or future (for example FHIR APIs) are EHRs expected to support multiple standard formats? Requiring support of multiple formats can be burdensome and costly.

(Page 7442) iv. Clinical Notes

Text:

The USCDI v1 includes a new data class, titled ''clinical notes.'' ''Clinical notes'' is included in the USCDI v1 based on significant feedback from the industry since the 2015 Edition final rule. We also received feedback during the Trusted Exchange Framework and Common Agreement (TEFCA) stakeholder sessions and public comment period. It has been identified by stakeholders as highly desirable data for interoperable exchange. The free text portion of the clinical notes was most often relayed by clinicians as the data they sought, but were often missing during electronic health information exchange. Clinical notes can be composed of text generated from structured (pick-list and/or check the box) fields as well as unstructured (free text) data. A clinical note may include the assessment, diagnosis, plan of care and evaluation of plan, patient teaching, and other relevant data points. We recognize that a number of different clinical notes could be useful for stakeholders. It is our understanding that work is being done in the community to focus on a subset of clinical notes. We considered three options for identifying the different ''note types'' to adopt in USCDI v1. The first option we considered would allow for the community to offer any and all recommended notes. The second option we considered would set a minimum standard of eight note types. This option was derived from the eight note types identified by the Argonaut Project participants[2]. The third option we identified would look to the eleven HL7 Consolidated Clinical Data Architecture (C–CDA) document types identified in the C–CDA Release 2.1, which also included the note types being identified by the Argonaut Project participants. We ultimately decided to move forward with the second option because it unites public and private interests toward the same goal. The eight selected note types are a minimum bar and, in the future, the USCDI may be updated to include other clinical notes. Specifically, we propose to include the following clinical note types for both inpatient and outpatient (primary care, emergency department, etc.) settings in USCDI v1 as a minimum standard: (1) Discharge Summary note; (2) History & Physical; (3) Progress Note; (4) Consultation Note; (5) Imaging Narrative; (6) Laboratory Report Narrative; (7) Pathology Report Narrative; and (8) Procedures Note. We seek comment on whether to include additional note types as part of the USCDI v1.

Comment:

[1] HL7 VERSION 2.5.1 IMPLEMENTATION GUIDE: S&I FRAMEWORK LAB RESULTS INTERFACE, RELEASE 1 – US REALM [HL7 Version 2.5.1: ORU^R01] DRAFT STANDARD FOR TRIAL USE, July 2012

[2] 17 Link to the Clinical Notes Argonaut Project identified (to clarify: Seven bullets are listed, however, we split laboratory and pathology note types into their own note) *http://wiki.hl7.org/index.php?title=201805_Clinical_Notes_Track*.

The ARCH indicates the FHIR DocumentReference[5] resource for Clinical Notes. If Laboratory Report Narrative and/or Pathology Report Narrative are included in the USCDI as additional clinical note types, we suggest the FHIR Resource used should be the DiagnosticReport[3] if the intent is to include the actual content contained in the laboratory or pathology report, vs. referring to the report(s) using the FHIR DocumentReference resource[4] (i.e. referring to a PDF, C-CDA, etc.).

As you finalize this ruling, you may want to consider the impact of laboratory results being shared with the patient from different sources due to potential for varying vocabularies (such as SNOMED, LOINC, RxNORM), standards formats, and result statuses as potential impacts to the data. Information sent to payers are not subject to the same regulatory requirements that exist between laboratories and the ordering/attending provider. Potential disparities in how the data is displayed and stored in these systems may further construe the information shared with the patient. We are concerned this may cause a patient safety risk.

We recommend that patient laboratory results be rendered to the patient from their ordering/attending provider as their trusted primary health care provider as data sent to the plan is traditionally for payment and not patient care.

(Page 7442-7443) v. Provenance

Text:

The USCDI v1 also includes a new data class, titled ''provenance.'' ''Provenance'' has been identified by stakeholders[5] as valuable for interoperable exchange. The provenance of data was also referenced by stakeholders as a fundamental need to improve the trustworthiness and reliability of the data being exchanged. Provenance describes the metadata, or extra information about data, that can help answer questions such as when and who created the data.

The inclusion of ''provenance'' as a data class in the USCDI v1 would also complement the Cures Act requirement to support the exchange of data through the use of APIs. This approach differs from the exchange of data via the C–CDA. While C–CDAs are often critiqued due to their relative ''length,'' the C–CDA represents the output of a clinical encounter and includes relevant context. The same will not always be true in an API context. APIs facilitate the granular exchange of data and, as noted in the 2015 Edition final rule, offer the potential to aggregate data from multiple sources in a web or mobile application (80 FR 62675). The inclusion of provenance would help retain the relevant context so the recipient can better understand the origin of the data. As noted in section VII.B.4, we are also proposing to include provenance in our proposed ''API Resource Collection in Health'' (ARCH) Version 1 implementation specification in § 170.215(a)(2), which would list a set of base Fast Healthcare Interoperability Resources (FHIR®) resources that Health IT Modules certified to the proposed API criterion (§ 170.315(g)(10)) would need to support.

We propose to further delineate the provenance data class into three data elements: ''the author,'' which represents the person(s) who is responsible for the information; ''the author's time stamp,'' which indicates the time the information was recorded; and ''the author's organization,'' which would be the organization the author is associated

[3] http://www.hl7.org/fhir/diagnosticreport.html
[4] **http://www.hl7.org/fhir/documentreference.html**
[5] 18 https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-commonagreement.

with at the time they interacted with the data. We have identified these three data elements as fundamental for data recipients to have available and both are commonly captured and currently available through standards. We request comment on the inclusion of these three data elements and whether any other provenance data elements, such as the identity of the individual or entity the data was obtained from or sent by (sometimes discussed in standards working groups as the provenance of the data's ''last hop''), would be essential to include as part of the USCDI v1 standard. We acknowledge that there is currently work to help define provenance in a standard robust manner, and we anticipate adopting the industry consensus once it becomes available.

Comment:

Please clarify how will you manage data created prior to 'enactment' of requiring provenance tracking, e.g. if effective January 1, 2021, how would you know data was created prior to that effective date and thus exempt from the provenance tracking requirements? This would require significant development to implement. We suggest the 24-month implementation timeframe should begin with the following calendar year. For example, if the final rule is published July 2020, the rule should be effective January 1, 2023. This will synch with CMS payment year if there are any CMS implications.

(Page 7447) a. Patient Access

Text:

…

As previously defined under the Program, "user" is a health care professional or his or her office staff; or a software program or service that would interact directly with the certified health IT (80 FR 62611, 77 FR 54168). We typically would expect the "user" in this case to be a provider or his or her office staff who will be performing the request on behalf of the patient given that a request of this nature would likely occur in the context of an individual exercising their right of access under the HIPAA Privacy Rule (45 CFR 164.524). In this regard, the proposed 2015 Edition "EHI export" criterion could facilitate and support the provision of a patient's record in an electronic format. In service to innovative and patient-centric approaches, a health IT developer could develop a method that allows the patient using a technology application (e.g., portal or "app") to execute the request without needing a provider to do so on their behalf. We seek comment on whether this portion of the criterion should be made more prescriptive to only allow the patient and his or her authorized representative to be the requestor of their EHI, similar to how we have previously scoped such criteria as "view, download, and transmit to 3rd party" (§ 170.315(e)(1)).

Similar to the 2015 Edition "data export" certification criterion (§ 170.315(b)(6)), which we propose for removal below, we acknowledge potential privacy and security concerns may arise when EHI is exported and, therefore, propose that for provider-mediated requests, a developer may design the health IT to limit the type of users that would be able to access and initiate EHI export functions. However, as we previously specified in the 2015 Edition final rule, the ability to "limit" the single patient EHI export functionality is intended to be used by and at the discretion of the provider organization implementing the technology, not a way for health IT developers to implicitly prevent the overarching user-driven aspect of this capability (80 FR 62646).

Comment:

We suggest the patient access eHI export should be restricted to the patient or the patient's authorized representative. Please ensure the same language referencing HIPAA is shared between the CMS, ONC and TEFCA rules.

(Page 7466-7467) d. Trusted Exchange Framework and the Common Agreement – Request for Information

Text:

…

We request comment as to whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI.

…

In consideration of this request for comment, we welcome comment on the certification criteria we have identified as the basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, other certification criteria that would serve as a basis for health IT developer participation in the Trusted Exchange Framework and adherence to the Common Agreement, and whether the current structure of the Trusted Exchange Framework and Common Agreement are conducive to health IT developer participation and in what manner.

Comment:

Please clarify that existing point to point interfaces, such as those developed to meet ONC Edition 2014 EHR certification for laboratory results, do not need to be replaced to meet requirements of the Cures Act.

Additionally, references to all Electronic Health Information (EHI) existing in the Qualified Health Information Network (QHIN) may create expectation that laboratories will send a copy of patient's laboratory results directly to a QHIN. We do not concur with this assumption, since, given existing ONC use cases for laboratory results, the patient's result is sent to the patient's provider's EHR system. The EHR system should forwarded patient data to the QHIN. We believe that Laboratory Information Systems (LIS) (e.g. a class of "certain health IT developer") should not be required to participate in QHINs, as they are reporting laboratory results to the provider's EHR system. LIS systems, are subject to CLIA accreditation, but are not mandated to comply with ONC EHR certification. We do not view this as "Information Blocking", as the laboratory result information is available from the provider's EHR system.

Multiple deliveries of the same data will have a negative impact on the quality of the data, and potentially may impede patient safety if not managed properly. Additionally, having multiple deliveries of the same data carries with it the additional risk of data breach. The more deliveries of data that you have … the greater the risk of some sort of security incident.

We would like the agency to consider requiring the patient's ordering/attending provider to submit all occurrences of the patient's result, including varying status (Preliminary, Final, Corrected, Canceled) and any other changes to ensure the patient is able to retrieve the latest occurrences of their laboratory result for sharing within their care team.

(Page 7477) c. Proposed API Standards, Implementation Specifications, and Certification Criterion and i. Proposed Adoption of FHIR DSTU2 Standard

Text:

…

APIs can be thought of as a set of commands, functions, protocols, and/or tools published by one software developer (''software developer A'') that enable other software developers (X, Y, and Z) to create programs and applications that interact with A's software without needing to know the ''internal'' workings of A's software. APIs can facilitate more seamless access to health information and it is important to note for context that ONC adopted three 2015 Edition certification criteria that specified API capabilities for Health IT Modules (criteria adopted in 45 CFR 170.315(g)(7), (g)(8), and (g)(9)). The following sections detail our proposals to adopt standards, implementation specifications, and a new API certification criterion. Together, these proposals account for the technical requirements we propose to associate with the Cures Act's API Condition of Certification and are reinforced through the condition's policy proposals.

…

Specifically, we propose to adopt FHIR Draft Standard for Trial Use (DSTU) 2 (hereafter referred to as ''FHIR Release 2'') as a baseline standard conformance requirement. In so doing, we can work with industry to support a conformance testing infrastructure for a full suite of proposals focused on one FHIR release (its associated implementation specifications) and complementary security and app registration protocols, compared to numerous versions.[6] The 2015 Edition final rule did not include specific standards or implementation specifications to describe the way in which APIs needed to be designed to meet § 170.315(g)(8).

…

Additionally, as discussed in further detail below, we reference FHIR Release 2 for use in the new API certification criterion proposed for adoption in § 170.315(g)(10). Although FHIR Release 3 is published and some health IT developers have ''normative'' for the first time. This will lead to a cycle of more mature US FHIR Core profiles aligned with Release 4 and additional implementation guidance that explicitly specifies how to handle populations of patient data (batch exports) via FHIR to more efficiently enable population and learning health system-oriented services.

…

We highly encourage stakeholders to express their perspective and explicitly note their preferred option in comments.

Comment:

We prefer the flexibility, similar to Option 3, to support both FHIR Release 2, Release 3 and/or Release 4. For laboratory reporting, the Observation Resource in Release 4 is more robust (and normative) so it offers benefits over Release 2 and Release 3.

We would like to suggest a different variant than the mandatory transition to FHIR Release 4. If trading partners have a functional installed interface using FHIR Release 2 or 3, how does it "reduce burden" to require them to "rip and replace" functional interoperability, and to require providers to upgrade an interface if it is not necessary? Therefore, we suggest that ONC permit trading partners and their clients to move to a later release when they agree there is justification to do so, for example additional data/improved functionality is available. There should be a tangible benefit offsetting the cost (time, resources and money) to upgrade an interface. Changes to existing laboratory interfaces could become timely as re-certification would also require an additional CLIA certification cycle.

[6] 81 In October 2018, ONC released a first version of a FHIR testing tool visit here for more details: *https://inferno.healthit.gov/*.

We realize this would require ONC to support certification of multiple versions of standards/implementation guides/etc. but hopefully this would not be an undue burden to ONC.

(Page 7497-7498) Standards Version Advancement Process

Text:

…

We have also been informed by stakeholders that, in other cases, ONC's inability to more nimbly identify and incorporate newer versions to standards and implementation specifications that were already adopted by the Secretary into the Program has perversely impacted standards developing organization (SDO) processes. Although SDOs can rapidly iterate version updates to standards and implementation specifications to address ambiguities and implementation challenges reported from the field and to particularly address matters that adversely impact interoperability, the lack of a clear path for that work effort to be timely realized as part of the Program's certification requirements has had a chilling effect on the pace of change. It can also affect the willingness of volunteers at these SDOs to devote their time to make updates that would be outdated by the time ONC goes through a rulemaking, which can be years. Stakeholders have indicated that certified health IT developers, customers and users of certified health IT, and the SDO industry have been technologically restricted and innovation-stunted as a result of our prior regulatory approach, which focused on certification assuring compliance only to the version of a standard adopted in regulation and did not provide an avenue for the Program to accommodate iterative updates to standards during the time between rulemakings. With the passage of the ''maintenance of certification'' provision in § 4002 of the Cures Act, we believe the approach proposed here is in line with our new statutory authority regarding Conditions of Certification and Maintenance of Certification and would better and more timely support market demands for widespread interoperability.

…

In order to attempt to keep pace with such updates, which are published at different times of the year, ONC would need to continuously engage in rulemaking cycles, perhaps even more than once per year. We believe that the proposed Standards Version Advancement Process would allow for more advanced versions of standards and implementation specifications to be approved for use under the Program in a more timely and flexible manner that helps to ease the concerns stakeholders have reported. Stakeholder input throughout the Program's existence has informed ONC that updating large groupings of standards' versions while also adopting new standards through rulemakings that only occur about once every three years can create an artificial market impact in a number of ways. Such ''all-in-one'' updates affect all health IT developers and the vast majority of health care providers at the same time across all sectors rather than enabling a more incremental and market-based upgrade cycle in response to interoperability, business, and clinical needs.

Comment:

We endorse ONC's proposal to adopt a "…more incremental and market based upgrade cycle…" and recognize the value in adopting later versions of standards in many interoperability scenarios. However, we would like to suggest that, If trading partners have a functional installed interface it does not "reduce burden" to require them to "rip and replace" functional interoperability, and to require providers to upgrade an interface if it is not necessary. Therefore, we suggest that ONC permit trading partners and their clients to move to a later release when they agree there is justification to do so, for example additional data/improved functionality is available. There should be a tangible

benefit offsetting the cost to upgrade an interface. Additionally, we recommend any changes to established and in-use standards support backwards compatibility with considerations for new functions requiring additional testing. We realize this would require ONC to support certification of multiple versions of standards/implementation guides/etc. but hopefully this would not be an undue burden to ONC.

The voluntary adoption approach ONC proposes for "Advanced Version Approval Approach" should provide pragmatic industry direction on the adoption of later versions/emerging standards. If the percentage of voluntary adoption is below 75% (for example), this could signal that industry should not be forced to move to the later version because it may not make business sense (e.g. no ROI) for the remaining 25%.

We believe that real world testing between systems should exclude real patient data as PHI must be protected.

(Page 7500-7501) Advanced Version Approval Approach

Text:

…

We welcome comments on any and all aspects of our proposed standards available to developers through maintenance requirements as part of the real world testing Condition and Maintenance of Certification. This includes all aspects of our described approach to standards and implementation specification advanced version approval processes. We also invite comments on our proposal to allow in conjunction with this maintenance flexibility the opportunity for developers to elect to present health IT for initial testing and certification either to more advanced versions or the prior versions included in regulatory text as of the date the technology is presented.

Comment:

We encourage external input from appropriate industry groups, specifically the laboratory industry. Laboratory results are used in many medical decisions, however although laboratorians have previously applied for membership in ONC federal advisory groups such as HITAC, none have been appointed.

With respect to "30 to 60 days" days comment period (page 7500, 2nd column), we encourage a minimum of a 60-day comment period.

With respect to flexibility about the name and version track identifiers for adopted implementation specifications, often this level of detail is needed to locate the correct version of an implementation specification. You have included numerous hyperlinks in this proposed rule and in the ISA, and we strongly encourage this practice. Versions of implementation specifications may not be forwardly/backwardly compatible with each other, especially if the implementation specification is a constraint on a non-normative standard (which does not require compatibility, for example FHIR releases prior to Release 4 did not contain Normative content and non-normative content in FHIR is not required to be backward/forward compatible.)

With respect to "…versioning update rather than amounting to a novel specification", we suggest that these types of documents include the document's 'lineage' to aid implementers in identifying the prior version(s).
We acknowledge that a later version of an implementation specification generally offers improved functionality; however, it may not be functionality that improves interoperability. For example, in Meaningful Use Stage 1, ONC

cited the following Implementation Guide for public health reporting (published 2010): HL7 Version 2.5.1: Implementation Guide: Electronic Laboratory Reporting to Public Health (US Realm), Release 1 with Errata and Clarifications and ELR 2.5.1 Clarification Document for EHR Technology Certification (a.k.a. ELR.)

In the ISA for Electronic Transmission of Reportable Lab Results to Public Health Agencies, ONC has referenced a later version, published in 2018: HL7 Version 2.5.1 Implementation Guide: Laboratory Results Interface, Release 1 STU Release 3 - US Realm (a.k.a. LRI). This 2018 update combines the same content that was in the 2010 ELR to handle as a profile in LRI. While we agree this may be an improved implementation approach for new EHR systems and interfaces, the decision for every public health department and laboratory to upgrade existing functional interfaces should be left to them. Trading partners should not be forced to "rip and replace" if the existing interface is functional and meets interoperability requirements between the trading partners.

(Page 7510) 1. Health Care Providers, Health IT Developers, Exchanges, and Networks

a). Health Care Providers

Text:

The term ''health care provider'' is defined in section 3000(3) of the PHSA. We propose to adopt this definition for purposes of section 3022 of the PHSA when defining ''health care provider'' in § 171.102. We note that this definition is different from the definition of ''health care provider'' under the HIPAA Privacy and Security Rules. We are considering adjusting the information blocking definition of ''health care provider'' to cover all individuals and entities covered by the HIPAA ''health care provider'' definition. We seek comment on whether this approach would be justified, and commenters are encouraged to specify reasons why doing so might be necessary to ensure that the information blocking provision applies to all health care providers that might engage in information blocking.

Comment:

We recommend considerations of laws and regulations at the federal and state level regarding restriction of laboratory results sharing; such as Patient and/or Test types. EHR systems will need to know which takes precedence. For example, states handle patient opt-in and opt-out rules differently which can include by patient overall or even by test type (mental health, HIV testing, Pregnancy, etc.).

(Pages 7513-7514) 3. Electronic Health Information; Price Information

Text:

The fragmented and complex nature of pricing within the health care system has decreased the efficiency of the health care system and has had negative impacts on patients, health care providers, health systems, plans, plan sponsors and other key health care stakeholders. Patients and plan sponsors have trouble anticipating or planning for costs, are not sure how they can lower their costs, are not able to compare costs, and have no practical way to measure the quality of the care or coverage they receive relative to the price they pay. Pricing information continues to grow in importance with the increase of high deductible health plans and surprise billing, which have resulted in an increase in out-of-pocket health care spending. Transparency in the price and cost of health care would help address the concerns outlined above by empowering patients to make informed health care decisions. Further, the availability of price information could help increase competition that is based on the quality and value of the services patients receive. Consistent with its statutory authority, the Department is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers.

Increased consumer demand, aligned incentives, more accessible and digestible information, and the evolution of price transparency tools are critical components to moving to a health care system that pays for value. However, the complex and decentralized nature of how price information is created, structured, formatted, and stored presents many challenges to achieving price transparency.

To this point, pricing within health care demands a market based
approach whereby, for example, platforms are created that utilize raw data to provide consumers with digestible price information through their preferred medium. ONC has a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information. Given that price information impacts the ability of patients to shop for and make decisions about their care, we seek comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking. In addition, the overall Department seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.

Should prices that are included in EHI:

Question:

- Reflect the amount to be charged to and paid for by the patient's health plan (if the patient is insured) and the amount to be charged to and collected from the patient (as permitted by the provider's agreement with the patient's health plan), including for drugs or medical devices;

Comment:

- Yes; these should be the full details including the deductible, co-insurance fees

Question:

- Include various pricing information such as charge master price, negotiated prices, pricing based on CPT codes or DRGs, bundled prices, and price to payer;

Comment:

- Laboratories could support a "list price" which would not factor in insurance reimbursement if the patient is insured. Since the patient results may trigger additional testing (with additional fee) it is difficult to calculate the price in advance.
- "List price" could convey the "highest cost", e.g. test trigger additional test/expense.

Question:

- Be reasonably available in advance and at the point of sale;

Comment:

- Yes, with caveat that future fiscal/calendar year price changes may not be readily available.

Question:

- Reflect all out-of-pocket costs such as deductibles, copayments and coinsurance (for insured patients); and/or

Comment:

- Yes

Question:

- Include a reference price as a comparison tool such as the Medicare rate and, if so, what is the most meaningful reference?

Comment:

- The CMS published Medicare reimbursement rate may not be aligned with private pay insurance policies. Displaying the Medicare rate should be labeled as 'Example Medicare' so it is not confusing to non-Medicare patients whose deductible/co-insurance/reimbursement may be different with a different payer.

Question:

- For the purpose of informing referrals for additional care and prescriptions, should future rulemaking by the Department require health IT developers to include in their platforms a mechanism for patients to see price information, and for health care providers to have access to price information, tailored to an individual patient, integrated into the practice or clinical workflow through APIs?

Comment:

- We suggest this info should come direct from the source (e.g. the care provider) vs. the health IT system.

To the extent that patients have a right to price information within a reasonable time in advance of care, how would such reasonableness be defined for:

Question:

- Scheduled care, including how far in advance should such pricing be available for patients still shopping for care, in addition to those who have already scheduled care;

Comment:

- Immediately, if from the source, e.g. the care provider, but with the caveat that prices may change for the future, especially fiscal or calendar year price as the price is subject to change according to the service date.

Question:

- How would price information vary based on the type of health insurance and/or payment structure being utilized, and what, if any, challenges would such variation create to identifying the price information that should be made available for access, exchange, or use?

Comment:

- The insurance reimbursement amount is pertinent to the patient, e.g. what the patient does (or does not) owe the provider is a factor of their insurance coverage, while the actual price may be more or less that the amount the insurance company agrees to reimburse. All costs needed to care for the patient should be made available, including ancillary charges such as laboratory, radiology, and/or anesthesiology.

Question:

- Are there electronic mechanisms/ processes available for providing price information to patients who are not registered (*i.e.,* not in the provider system) when they try to get price information?

Comment:

- Unknown, but we suggest this info should come direct from the source (e.g. the care provider) vs. the health IT system.

Question:

- Should price information be made available on public websites so that patients can shop for care without having to contact individual providers, and if so, who should be responsible for posting such information?
- Additionally, how would the public posting of pricing information through API technology help advance market competition and the ability of patients to shop for care?

Comment:

- Payers contract coverage/reimbursement with providers, so it seems the information should be available from providers. The entity setting the price should be responsible for posting.
- This might benefit self-pay patients, but insured patients may be required to see specific "in network" providers for the service to be covered.

Question:

- Would updates to the CMS managed HIPAA transactions standards and code sets be necessary to address the movement of price information in a standardized way?

Comment:

- We suggest FHIR APIs might be a preferable standard for this use case.

If price information is included in EHI, could that information be useful in subsequent rulemaking that the Department may consider in order to reduce or prevent surprise medical billing, such as requirements relating to:

Question:

- The provision of a single bill that includes all health care providers involved in a health care service, including their network status.

Comment:

- We recommend more clarity on what a 'health care service' includes before this can be addressed.

Question:

- The provision of a binding quote reasonably in advance of scheduled care (that is, non-emergent care) or some subset of scheduled care, such as for the most ''shoppable'' services;

Comment:

- Not all services are predicable in advance; for example, some laboratory tests may produce a result that triggers additional tests thus the cost cannot be known until the initial test is processed. Therefore, exception process would need to be defined.

Question:

- Ensuring that all health care providers in an in-network facility charge the in-network rate; and

Comment:

- Yes, this would be valuable to the patient.

Question:

- Notification of billing policies such as timely invoice dates for all providers and facilities, notwithstanding network status, due date for invoice payments by the prospective patient's payers and out of-pocket obligations, date when unpaid balances are referred for collections, and appeals rights and procedures for patients wishing to contest an invoice?

Comment:

- Yes

(Page 7514) Interests Promoted by the Information Blocking Provision

a) Access, Exchange, and Use of EHI (Page 7514)

b) Interoperability Elements (Page 7515)

Text:

In this proposed rule, we use the term ''interoperability element'' to refer to any means by which EHI can be accessed, exchanged, or used. We clarify that the means of accessing, exchanging, and using EHI are not limited to functional elements and technical information but also encompass technologies, services, policies, and other conditions[7] necessary to support the many potential uses of EHI as described above. Because of the evolving nature of technology and the diversity of privacy laws and regulations, institutional arrangements, and policies that govern the sharing of EHI, we will not provide an exhaustive list of interoperability elements. However, we believe that it is useful to define this term, both because of its importance for analyzing the likelihood of interference under the information blocking provision, and because some of the proposed exceptions to the provision contain conditions concerning the availability and provision of interoperability elements. Therefore, we propose to define ''interoperability element'' in § **171.102**. As noted, our intent is to capture all of the potential means by which EHI may be accessed, exchanged, or used for any relevant purposes; both now and as technology and other conditions evolve. We seek comment on whether the proposed definition realizes that intent and, if not, any changes we should consider.

Comment:

Recommend the usage of definitions be combined as referencing multiple definitions can be confusing. Additionally, any referral to an external source needs to ensure the regulations remains static without dynamically changing.

(Pages 7522-7524) A. Proposed Exceptions to the Information Blocking Provision

Text:

…

[7] **108 *See* ONC, *Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap* at x–xi, *https://www.healthit.gov/topic/interoperability/interoperability-roadmap* (Oct. 2015) [hereinafter ''Interoperability Roadmap'']**.

We request comment on the following seven proposed exceptions, including whether they will achieve our stated policy goals.

(Page 7524) Risk of corrupt or inaccurate data being recorded or incorporated in a patient's electronic health record

…

Consistent with the definition of information blocking, we have identified certain risks to patient harm that arise in the context of access, exchange, or use of EHI. To qualify for this proposed exception, an actor's practice must respond to a risk that is cognizable under this exception.

…

We understand that in the ordinary course of practice, and consistent with professional and legal standards for clinical record keeping, health care providers take appropriate action to remediate known problems with EHI and restore a record as a whole to be safely usable, and therefore safely sharable.

This recognized risk is limited to corruption and inaccuracies caused by performance and technical issues affecting health IT. For example, this exception may be relevant if certified health IT were to incorrectly present an old and superseded version of a medication list, or when only partial **copies of laboratory tests are being** linked to a patient when the patient's record is exchanged. However, this recognized risk does not extend to purported accuracy issues arising from the incompleteness of a patient's electronic health record generally. Electronic health records, like the paper charts they replaced, are inevitably imperfect records. Many patients see multiple health care providers and so it is unlikely that any single health care provider's record will provide a complete picture of a patient's health.

Some patients intentionally keep certain information secret even from their health care providers, and others fail to share potentially critical information with their health care providers because they forget to, or simply do not understand its clinical significance.

…

Comment:

As a laboratory provider, we concur "…that partial copies of laboratory tests linked to a patient when the patient's record is exchanged…" are a concern, particularly when the initial test result triggers additional laboratory testing or patient specimens have been cultured which can take days or weeks to finalize test results. The preliminary laboratory results could present an incomplete picture of the patient's health. It is crucial for electronic health record (EHR), health information exchange (HIE), health information network (HIN) and other laboratory result 'amalgamation' systems to properly support the accurate interpretation of laboratory result status terminology in order to appropriately manage and display the results. For example, a final result replaces a preliminary result; a corrected result replaces a final result, etc. The 2012 HL7 Version 2.5.1 Implementation Guide: S&I Framework Lab Results Interface, Release 1 (LRI IG) adopted for Meaningful Use Stage 2 contained 9 result status codes; the 2018 update contains 10 supported Result Status codes (HL7 Table 0123).

Due to the complexities of accurately managing patients' laboratory results, we do not concur with sending laboratory results to HIE and HIN systems. The patient's result is sent to the patient's provider's EHR system, which is designed to appropriately manage laboratory result status. The provider's EHR system should forwarded appropriate patient data to the HIE and/or HIE systems. Multiple deliveries of the same data will have a negative impact on the quality of the data, and potentially may impede patient safety if not managed properly. Additionally, having multiple deliveries of the same data carries with it the additional risk of data breach. The more deliveries of data that you have … the greater the risk of some sort of security incident.

As you finalize this ruling, you may want to consider the impact of laboratory results being shared with the patient from different sources due to potential for varying vocabularies (such as SNOMED, LOINC, RxNORM), standards formats, and result statuses as potential impacts to the data. Information sent to payers are not subject to the same regulatory requirements that exist between laboratories and the ordering/attending provider. Potential disparities in how the data is displayed and stored in these systems may further construe the information shared with the patient. We are concerned this may cause a patient safety risk.

We recommend that patient laboratory results be rendered to the patient from their ordering/attending provider as their trusted primary health care provider as data sent to the plan is traditionally for payment and not patient care.