May 29, 2015

Submitted Electronically

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National Coordinator for Health Information Technology
Office of the Secretary, Department of Health and Human Services
200 Independence Ave., S.W., Room 7-729D
Washington, D.C. 20201


Dear Dr. DeSalvo:

Thank you for the opportunity to submit comments on the “2015 Edition Health IT Certification Criteria, 2015 Base EHR Definition, and ONC Health IT Certification Program Modifications.”

As you know well, health data will transform health and health care, but change cannot happen soon enough.

The Health Data Consortium (HDC) sits at the intersection of health data, innovation and public policy. HDC is a public-private consortium focused on promoting the accessibility, availability and responsible use of health data and encourages collaboration among health data users and stakeholders to ignite innovation, drive down rising health care costs and improve patient outcomes. We bring together a diverse group of stakeholders including patient advocates, providers, researchers, industry representatives, innovators, and policymakers to advance the national dialogue surrounding the key barriers and opportunities in using health data. Since its formation, HDC has focused on a number of important cultural, technical, and public policy issues concerning health data, including data governance, data accessibility, privacy and security and consumer engagement.

HDC is committed to advancing health data accessibility, liberation and liquidity. In general, HDC believes that any certification criteria that is implemented must not be overly prescriptive to allow innovation to flourish within health IT. Additionally, the certification criteria should be properly aligned with what is achievable in the marketplace today.

Although the 2015 Edition proposed rule covers many important topics, we have focused our comments below on a number of specific issues that we believe are critical to advancing health data accessibility, liberation and liquidity. We also have provided suggestions for additional strategies to be considered for inclusion.

A. Provisions of the Proposed Rule affecting Standards, Implementation Specifications, Certification Criteria, and Definitions

<table>
<thead>
<tr>
<th>§ 170.315(a)(19) Patient health information capture</th>
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<tbody>
<tr>
<td><strong>Included in 2015 Edition Base EHR Definition?</strong></td>
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<tr>
<td>No, but proposed for the EHR Incentive Programs CEHRT definition</td>
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<tr>
<td>Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient’s care.</td>
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<tr>
<td>(1) <strong>Patient health information capture.</strong> Technology must be able to enable a user to:</td>
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<td>(i) Identify, record, and access patient health information documents;</td>
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<td>(ii) Reference and link to patient health information documents; and</td>
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<td>(iii) Record and access information directly shared by a patient.</td>
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<td><strong>Preamble FR Citation:</strong> 80 FR 16823</td>
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<td><strong>Specific questions in preamble? No</strong></td>
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**Public Comment Field:**

HDC appreciates that ONC proposes to require a Health IT Module to demonstrate that it could enable a user to record and access information from multiple sources directly and electronically shared by a patient. As you know, there are many different types of health data being collected besides traditional electronic health record (EHR) information. These include data from medical devices, clinical trials, clinical registries as well as mobile health and wearable technologies. The volume of health data is expected to continue to grow exponentially in the future. In fact, it is projected that an estimated 50 billion connected devices will be available globally by 2020—approximately six devices per person, many of which will have the ability to collect usable data.\(^1\) Patient-generated data may only tell one part of a patient’s story, but when combined with other data sources collected over time, it begins to paint a longitudinal picture of an individual’s medical history that is a more accurate reflection of an individual’s real-time, real-world experience rather than distinct data points collected at discrete intervals in a clinical setting. Requiring certification criterion that would enable a user to record and access information directly shared by a patient could help accelerate a more complete picture of a patient’s medical history which in turn could result in better care coordination and collaboration.

HDC also appreciates that ONC has not proposed specific standards related to receiving and accepting information directly and electronically shared by a patient. Structured data elements are a critical component to improving data accessibility throughout the ecosystem. However, requiring data that is collected in different contexts to be too standardized at this juncture may cause providers to lose the patient’s narrative, creating a “loss of signal.”

§ 170.315(a)(20) Implantable device list

| Included in 2015 Edition Base EHR Definition? | Yes |
| Stage 3 MU Objective | N/A |
| 2015 Edition Health IT Certification Criterion | |

(2) Implantable device list.

(i) Enable a user to record, change, and access, a list of Unique Device Identifiers associated with a patient’s Implantable Device(s).

(ii) Parse the following data elements from a Unique Device Identifier:

- (A) Device Identifier;
- (B) Batch/lot number;
- (C) Expiration date;
- (D) Production date; and
- (E) Serial number.

(iii) Retrieve the “Device Description” attribute associated with a Unique Device Identifier in the Global Unique Device Identification Database.

(iv) For each Unique Device Identifier in a patient’s list of implantable devices, enable a user to access the following:

- (A) The parsed data elements specified under paragraph (a)(20)(ii) of this section that are associated with the UDI; and
- (B) The retrieved data element specified under paragraph (a)(20)(iii) of this section.

Preamble FR Citation: 80 FR 16824

Specific questions in preamble? Yes
§ 170.315(a)(20) Implantable device list

Public Comment Field:
HDC appreciates the inclusion of criterion focused on the ability of a Health IT Module: to record, change, and access a list of unique device identifiers (UDIs) corresponding to a patient’s implantable device, to parse certain data from a UDI, to retrieve “Device Description” attributes associated with a UDI in the Global Unique Device Identification Database (GUDID), and to make accessible to a user both parsed and retrieved data.

Including UDIs in a patient’s EHR would enable this information to be portable, thus allowing the data to travel with the patient. By allowing clinicians to access this information, UDIs could provide the information needed in the clinical setting and optimize device safety and effectiveness.² Recording UDIs in EHRs could also enhance the nation’s ability to conduct post-market medical device safety surveillance and manage recalls—resulting in more accurate reporting of adverse events, more effective allocation of resources to address device recalls and alerts, and improved patient safety.³

Furthermore, HDC supports the inclusion of a patient’s UDI(s) as data within the Common Clinical Data Set definition. Inclusion of a patient’s UDI(s) will help facilitate the exchange of UDIs across different vendor platforms as well as increase the availability and reliability of information about a patient’s implantable device(s).

§ 170.315(a)(21) Social, psychological, and behavioral data

Included in 2015 Edition Base EHR Definition?
No

Stage 3 MU Objective
N/A

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³ Id.
§ 170.315(a)(21) Social, psychological, and behavioral data

2015 Edition Health IT Certification Criterion

(3) **Social, psychological, and behavioral data.** Enable a user to record, change, and access, at a minimum, one of the following patient social, psychological, and behavioral data.

   (i) **Sexual orientation.** Enable sexual orientation to be recorded in accordance with the standard specified in § 170.207(o)(1) and whether a patient declines to specify sexual orientation.

   (ii) **Gender identity.** Enable gender identity to be recorded in accordance with the standard specified in § 170.207(o)(2) and whether a patient declines to specify gender identity.

   (iii) **Financial resource strain.** Enable financial resource strain to be recorded in accordance with the standard specified in § 170.207(o)(3) and whether a patient declines to specify financial resource strain.

   (iv) **Education.** Enable education to be recorded in accordance with the standard specified in § 170.207(o)(4) and whether a patient declines to specify education.

   (v) **Stress.** Enable stress to be recorded in accordance with the standard specified in § 170.207(o)(5) and whether a patient declines to specify stress.

   (vi) **Depression.** Enable depression to be recorded in accordance with the standard specified in § 170.207(o)(6) and whether a patient declines to specify stress.

   (vii) **Physical activity.** Enable physical activity to be recorded in accordance with the standard specified in § 170.207(o)(7) and whether a patient declines to specify physical activity.

   (viii) **Alcohol use.** Enable alcohol use to be recorded in accordance with the standard specified in § 170.207(o)(8) and whether a patient declines to specify alcohol use.

   (ix) **Social connection and isolation.** Enable social connection and isolation to be recorded in accordance the standard specified in § 170.207(o)(9) and whether a patient declines to specify social connection and isolation.

   (x) **Exposure to violence (intimate partner violence).** Enable exposure to violence (intimate partner violence) to be recorded in accordance with the standard specified in § 170.207(o)(10) and whether a patient declines to specify exposure to violence (intimate partner violence).

Preamble FR Citation: 80 FR 16826

Specific questions in preamble? Yes, and also see requests for comment on work information (industry/occupation) data and U.S.uniformed/military service data
§ 170.315(a)(21) Social, psychological, and behavioral data

Public Comment Field:
HDC appreciates the inclusion of certification criterion that requires a Health IT Module to be capable of enabling a user to record, change, and access a patient’s social, psychological, and behavioral data—including the ability to record a patient’s decision not to provide the information. Health is about more than just health care—it incorporates the social determinants of health which can include: (1) social factors—such as education and community safety, (2) economic factors—including income and employment and (3) environmental factors—such as air quality, transit and access to health care.4 In 2014, the Institute of Medicine (IOM) expanded the definition of social determinants of health to include psychological and behavioral data.5 The inclusion of social, psychological and behavioral data in EHRs could help provide a comprehensive picture of a patient’s health and health care, as well as enhance clinical decision-making and improve population health.

HDC also believes there is persuasive evidence to suggest that there should be certification criterion that requires Health IT Modules to enable a user to record, change, and access U.S. military service information. HDC recognizes that the vocabulary standards for capturing this data may not be mature enough at this point in time. However, last year, of the 21.6 million living veterans, only 6.6 million received services through the Veterans Health Administration (VHA)—meaning that a majority of veterans are receiving care outside of the VHA.6 Enabling a user to record, change and access U.S. Military Service information will improve the flow of data throughout the health ecosystem and help produce a better longitudinal record of care for a U.S. service member. Furthermore, access to such data can help identify epidemiological risks for patients and ensure that a patient receives the benefits he or she is entitled to by alerting medical professionals to the patient’s service history which could help facilitate the administration of benefits.

§ 170.315(b)(6) Data portability

Included in 2015 Edition Base EHR Definition?
Yes

Stage 3 MU Objective
N/A

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5 Id.

§ 170.315(b)(6) Data portability

2015 Edition Health IT Certification Criterion

(1) Data portability.
   (i) General requirements for export summary configuration. A user must be able to set the following configuration options when using technology to create an export summary or set of export summaries for patients whose information is stored in the technology. A user must be able to execute these capabilities at any time the user chooses and without subsequent developer assistance to operate.

   (ii) Document creation configuration.
       (A) Document-template types. A user must be able to configure the technology to create an export summary or export summaries formatted according to the standard adopted at § 170.205(a)(4) for any of the following document-template types.

           (1) Generally applicable. CCD; Consultation Note; History and Physical; Progress Note; Care Plan; Transfer Summary; and Referral Note.

           (2) Inpatient setting only. Discharge Summary.

       (B) For any document-template selected the technology must be able to include, at a minimum, the Common Clinical Data Set and the following data expressed, where applicable, according to the specified standard(s):

           (1) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard at § 170.207(a)(4);

           (2) Cognitive status;

           (3) Functional status;

           (4) Ambulatory setting only. The reason for referral; and referring or transitioning provider’s name and office contact information; and

           (5) Inpatient setting only. Discharge instructions.

       (C) Use of the “unstructured document” document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

   (iii) Timeframe configuration. A user must be able to configure the technology to set the time period within which data would be used to create the export summary or summaries. This must include the ability to enter in a start and end date range as well as the ability to set a date at least three years into the past from the current date.

   (iv) Event configuration. A user must be able to configure the technology to create an export summary or summaries based on the following user selected events:

       (A) A relative date or time (e.g., the first of every month);

       (B) A specific date or time (e.g., on 10/24/2015); and

       (C) When a user signs a note or an order.

   (v) Location configuration. A user must be able to configure and set the storage location to which the export summary or export summaries are intended to be saved.

Preamble FR Citation: 80 FR 16839

Specific questions in preamble? No

Public Comment Field:

In general, HDC appreciates that the data portability certification criterion requires a Health IT Module to enable a user to independently execute this capability without assistance from the health IT developer beyond normal orientation and training. A common frustration that HDC has heard from stakeholders is that while some health IT developers provide data portability capabilities, it is can be difficult to find and/or use, non-intuitive, requires additional health IT developer staff to assist the provider in executing the action or it is performed only by the developer at the provider’s request. Such constraints hinder data accessibility and impairs clinical decision making and care coordination by limiting the flow of data.
### § 170.315(e)(1) View, download, and transmit to a third party

<table>
<thead>
<tr>
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<tbody>
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#### Stage 3 MU Objectives

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient’s care.
2015 Edition Health IT Certification Criterion

(1) **View, download, and transmit to 3rd party.**

(i) Patients (and their authorized representatives) must be able to use technology to view, download, and transmit their health information to a 3rd party in the manner specified below. Access to these capabilities must be online and through a secure channel that ensures all content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).

(A) **View.** Patients (and their authorized representatives) must be able to use health IT to view in accordance with the standard adopted at § 170.204(a)(1), at a minimum, the following data:

(1) The Common Clinical Data Set (which should be in their English (i.e., non-coded) representation if they associate with a vocabulary/code set).

(2) **Ambulatory setting only.** Provider's name and office contact information.

(3) **Inpatient setting only.** Admission and discharge dates and locations; discharge instructions; and reason(s) for hospitalization.

(4) **Laboratory test report(s).** Laboratory test report(s), including:

   (i) The information for a test report as specified all the data specified in 42 CFR 493.1291(c)(i) through (7);

   (ii) The information related to reference intervals or normal values as specified in 42 CFR 493.1291(d); and

   (iii) The information for corrected reports as specified in 42 CFR 493.1291(k)(2)

(5) **Diagnostic image report(s).**

(B) **Download.**

(1) Patients (and their authorized representatives) must be able to use EHR technology to download an ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) in only human readable format, in only the format specified in accordance to the standard adopted at § 170.205(a)(4), or in both formats. The use of the “unstructured document” document-level template is prohibited for compliance with the standard adopted at § 170.205(a)(4).

(2) When downloaded according to the standard adopted at § 170.205(a)(4), the ambulatory summary or inpatient summary must include, at a minimum, the following data (which, for the human readable version, should be in their English representation if they associate with a vocabulary/code set):

   (i) Ambulatory setting only. All of the data specified in paragraph (e)(1)(i)(A)(1), (2), (4), and (5) of this section.

   (ii) Inpatient setting only. All of the data specified in paragraphs (e)(1)(i)(A)(1), and (3) through (5) of this section.

(3) **Inpatient setting only.** Patients (and their authorized representatives) must be able to download transition of care/referral summaries that were created as a result of a transition of care (pursuant to the capability expressed in the certification criterion adopted at paragraph (b)(1) of this section).

(C) **Transmit to third party.** Patients (and their authorized representatives) must be able to:

(1) Transmit the ambulatory summary or inpatient summary (as applicable to the health IT setting for which certification is requested) created in paragraph (e)(1)(i)(B)(2) of this section in accordance with at least one of the following:

   (i) The standard specified in § 170.202(a).

   (ii) Through a method that conforms to the standard specified at § 170.202(d) and leads to such summary being processed by a service that has implemented the standard specified in § 170.202(a).

(2) **Inpatient setting only.** Transmit transition of care/referral summaries (as a result of a transition of care/referral) selected by the patient (or their authorized representative) in accordance with at least one of the following:

   (i) The standard specified in § 170.202(a).
§ 170.315(e)(1) View, download, and transmit to a third party

(ii) Activity history log.

(A) When electronic health information is viewed, downloaded, or transmitted to a third-party using the capabilities included in paragraphs (e)(1)(i)(A) through (C) of this section or when an application requests electronic health information using the capability specified at paragraph (e)(1)(iii) of this section, the following information must be recorded and made accessible to the patient:

1. The action(s) (i.e., view, download, transmission, API response) that occurred;
2. The date and time each action occurred in accordance with the standard specified at § 170.210(g);
3. The user who took the action; and
4. Where applicable, the addressee to whom an ambulatory summary or inpatient summary was transmitted.

(B) Technology presented for certification may demonstrate compliance with paragraph (e)(1)(ii)(A) of this section if it is also certified to the certification criterion adopted at §170.315(d)(2) and the information required to be recorded in paragraph (e)(1)(ii)(A) is accessible by the patient.

2015 Edition Health IT Certification Criterion, §170.315(e)(1) View, download, and transmit to 3rd party, continued

(i) Application access. Patients (and their authorized representatives) must be able to use an application that can interact with the following capabilities. Additionally, the following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(A) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(B) Patient selection. The API must include a means for the application to query for an ID or other token of a patient’s record in order to subsequently execute data requests for that record in accordance with (e)(1)(iii)(C) of this section.

(C) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:

1. Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

2. All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(D) Documentation. The API must include accompanying documentation that contains, at a minimum:

1. API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

2. The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(E) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.

Preamble FR Citation: 80 FR 16848        Specific questions in preamble? Yes
§ 170.315(e)(1) View, download, and transmit to a third party

Public Comment Field:
HDC appreciates that the “View, Download and Transmit to a Third Party” (VDT) criterion continues to clarify that patients and their authorized representatives have the ability to perform the VDT functionality. Allowing a patient and their authorized representative access to their health information in a timely manner will empower patients and their caregivers to make informed decisions about their health and health care.

HDC also supports ONC’s proposal to require that the capabilities proposed in the “Application Access to Common Clinical Data Set” at §170.315(g)(7) be met as part of the 2015 Edition VDT certification criterion. Because it is possible that a health IT developer may seek certification solely on the VDT criterion, this requirement will help encourage broad adoption of APIs by health IT developers as part of their technology.

§ 170.315(g)(7) Application access to Common Clinical Data Set

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**Stage 3 MU Objectives**

The EP, eligible hospital, or CAH provides access for patients to view online, download, and transmit their health information, or retrieve their health information through an API, within 24 hours of its availability.

Use communications functions of certified EHR technology to engage with patients or their authorized representatives about the patient’s care.
§ 170.315(g)(7) Application access to Common Clinical Data Set

2015 Edition Health IT Certification Criterion

(1) Application access to Common Clinical Data Set. The following technical outcomes and conditions must be met through the demonstration of an application programming interface (API) that can respond to requests from other applications for data specified within the Common Clinical Data Set.

(i) Security. The API must include a means to establish a trusted connection with the application requesting patient data, including a means for the requesting application to register with the data source, be authorized to request data, and log all interactions between the application and the data source.

(ii) Patient selection. The API must include a means for the application to query for an ID or other token of a patient’s record in order to subsequently execute data requests for that record in accordance with paragraph (g)(7)(iii) of this section.

(iii) Data requests, response scope, and return format. The API must enable and support both of the following data request interactions:

(A) Data-category request. The API must support syntax that allows it to respond to requests for each of the individual data categories specified in the Common Clinical Data Set and return the full set of data for that data category (according to the specified standards, where applicable) in either XML or JSON.

(B) All-request. The API must support syntax that allows it to respond to a request for all of the data categories specified in the Common Clinical Data Set at one time and return such data (according to the specified standards, where applicable) in a summary record formatted according to the standard adopted at § 170.205(a)(4).

(iv) Documentation. The API must include accompanying documentation that contains, at a minimum:

(A) API syntax, function names, required and optional parameters and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(B) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(v) Terms of use. The terms of use for the API must be provided, including, at a minimum, any associated developer policies and required developer agreements.
§ 170.315(g)(7) Application access to Common Clinical Data Set

Public Comment Field:
HDC supports the inclusion of new certification criterion that requires the demonstration of an application programming interface (API) that responds to data requests for any one or more of the data referenced in the Common Clinical Data Set definition, including requests for all of the data in the Common Clinical Data Set.

Digital health innovation is taking place within the health care industry, creating more opportunities to share data. By mid-2014, digital health funding approached $2.3 billion, a 170 percent increase over 2013.7 This trend is anticipated to continue with the market for digital health expected to surpass $200 billion by 2020.8 Increased use of APIs could help foster innovation by encouraging third-party entrepreneurs to innovate around patients and/or their caregivers by encouraging access to their personal health information.

APIs could also help make data more accessible and encourage broader data exchange across different platforms, software and devices. For that reason, HDC supports ONC’s proposal to require that this certification be a part of the criteria necessary to satisfy the “2015 Edition Base EHR” definition. Inclusion of this certification in the 2015 Base EHR definition may accelerate broader adoption of APIs which in turn will improve data accessibility, data liquidity and help ignite innovation in the health IT sector.

HDC also appreciates that §170.315(g)(7) broadly specifies the technical outcomes required under this criterion. To require too many technical outcomes at this juncture with respect to APIs, may hinder innovation, stifle competition among health IT developers and stagnate the market.

Common Clinical Data Set Definition

| Preamble FR Citation | 80 FR 16871 | Specific questions in preamble? | No |

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8 Id.
Common Clinical Data Set Definition

Public Comment Field:
As part of a learning health system, common formats are the bedrock of successful interoperability. To successfully move data from one stakeholder to another, the meaning of the information must be maintained and consistently understood as it travels.

In addition, for a learning health system to innovate, the industry will have to agree on the use of common content and vocabulary standards to satisfy each specific interoperability purpose. If we are to advance interoperability, stakeholders, both private and public, should agree to a standardized common clinical data set that is consistently and reliably shared during transitions of care. Having a standardized common clinical data set would establish a foundation and could be improved upon over time. Stakeholders must make progress on standards that could support the exchange of more structured, standardized and discrete information as to allow the data to be used and received by other systems. For that reason, HDC supports the inclusion of a Common Clinical Data Set in the 2015 Edition proposed rule that includes, among other information: demographics, vital signs, body mass index, and growth charts, problem list, medication list, medication allergy list, UIDs, smoking status, and image results, etc.

B. Provisions of the Proposed Rule Affecting the ONC Health IT Certification Program

The following comment tables are meant to capture proposals relevant to the ONC Health IT Certification Program.

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<td><strong>Preamble FR Citation:</strong> 80 FR 16880</td>
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## Transparency and Disclosure Requirements

### Public Comment Field:

HDC appreciates that ONC proposes to revise the principles of proper conduct for ONC-ACBs in order to provide greater and more effective disclosure by health IT developers of certain limitations and costs that could interfere with a user’s ability to use health IT in a manner consistent with its certification.

As you know well, a number of stakeholders, including Congress, have expressed concern that some health IT developers of certified health IT may be engaging in practices that block health information exchange.\(^9\) ONC itself has acknowledged that there is anecdotal evidence of information blocking by some health IT developers.\(^10\) In turn, these practices create a disincentive to share data outside of a health system or a provider’s office or practice.

Additional disclosure requirements could provide greater transparency during the procurement process such that purchasers of certified health IT systems would not be surprised by additional costs or expenses at the onset, nor would they encounter as many unexpected difficulties in the implementation and use of certified health IT. Improved transparency and disclosure may also reduce instances of users being “locked in” to a particular health IT system because the user would know of additional costs and expenses upfront. Such transparency may also foster competition and allow innovation to flourish by allowing health IT developers to compete based on consumer preferences. Additionally, it may encourage more entrepreneurs and innovators to enter the marketplace to address overlooked consumer preferences.

## “Decertification” of Health IT – Request for Comment

| Preamble FR Citation: 80 FR 16886 | Specific questions in preamble? | Yes |

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\(^9\) Pub. L. 113-235.

“Decertification” of Health IT – Request for Comment

Public Comment Field:
HDC appreciates the opportunity to offer comments on the “decertification” of Health IT. As mentioned above, potential information blocking by health IT developers remains a consistent concern for health IT adopters. In general, HDC believes that to encourage collaboration, data holders should avoid situations where (even when permissible by law), differences in fees, policies, services, operations or contracts prevent data exchange. Data holders and entities facilitating interoperability should also not establish policies or practices in excess of law that inhibit data accessibility by other entities that are in compliance with existing law and governance principles.

HDC understands and acknowledges that decertification of health IT has broad implications for a multitude of stakeholders. For that reason, prior to ONC issuing a separate rulemaking on decertification, we recommend that ONC convene a multi-stakeholder group comprised of: health IT developers, providers, hospitals, (including those participating in the EHR Incentive Programs), government, ONC-ACBs and consumers to fully understand the downstream implications of decertification of health IT. We also believe that implementation of a transparent, inclusive, multi-stakeholder governance model as proposed in the draft Shared Nationwide Interoperability Roadmap could play a crucial role not only in establishing “guardrails” or “rules of the road” for stakeholders to encourage health information exchange but could encourage transparency in the market and create a mechanism for ensuring that the various parties adhere to a common set of rules to help prevent occurrences of decertification of health IT products due to information blocking.

Should these practices fail to prevent information blocking, ONC may want to consider taking steps to “decertify” products that proactively block the sharing of information when, based on the facts and circumstances, a person(s) or entity(ies) knowingly and unreasonably interfere with the exchange or use of electronic health information in a manner that does not serve to protect patient safety, or maintain the privacy and security of an individual’s health information.

We thank you again for the opportunity to comment on the 2015 EHR Certification Edition. We look forward to working with ONC to further enhance the implementation strategies in achieving health IT interoperability. Should you or your staff have any additional questions or comments, please contact Lauren Ellis Riplinger, Director of Policy and Government Affairs at lellis@healthdataconsortium.org or at 202-292-6784.

Sincerely,

Dr. Christopher Boone, PhD, FACHE
Chief Executive Officer
Health Data Consortium