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May 29, 2015

Dr. Karen DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
200 Independence Ave., SW
Washington, D.C. 20201

Attn.: 2015 Edition EHR Standards and Certification Criteria Proposed Rule

re: American Cancer Society Cancer Action Network Comments on Proposed Rulemaking – RIN 0991-AB93 – 2015 Edition Health Information Technology Certification Criteria

Dear Dr. DeSalvo:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the 2015 Edition Health IT Certification Proposed Rule. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society, and supports evidence-based policy and legislative solutions designed to eliminate cancer as a major health problem. As the nation's leading advocate for public policies that are helping to defeat cancer, ACS CAN ensures that cancer patients, survivors, and their families have a voice in public policy matters at all levels of government.

In 2015, there will be an estimated 1,658,370 new cancer cases diagnosed and 589,430 cancer deaths in the U.S. Health information technology (IT) has the potential to improve how successfully we prevent, treat, and beat cancer by enabling more data-driven decision making on the part of patients, physicians and public health professionals. These proposed regulations are a very important step to ensure that health IT facilitates better care and better health, and reflect a commitment to meeting the needs of cancer patients and their families.

Overall, the proposed regulations will advance the technological capacity to support cancer patients across the care continuum by allowing patients timely access to their health information. By introducing the "Application Access to Common Clinical Data Set" criterion, patient access to, and use of, their health information will be available whenever and wherever needed as patients navigate across the care continuum. The proposed criterion also facilitate the movement towards patient-centered care through capture of critical information about individuals' health and care outside the clinical setting that is crucial for cancer prevention and quality of care (e.g., social determinants of health and health information documents such as advance directives.). Further, utilizing a more granular, standardized definition of race and

ethnicity in the "demographics" criterion improves the ability of practitioners to identify, understand, and reduce health disparities that can lead to decreased cancer rates.

How ONC defines and alters the 2015 edition criteria matters and affects cancer patients and their families. Defining the "Care Plans" criterion to include patients' goals, and patients' and family caregivers' health concerns, greatly improves the relevant health information available to providers, patients and family caregivers for shared decision-making that is at the core of improving the quality of cancer care.[1] However, despite these changes, questions regarding the alignment across the 2015 edition criteria and the Stage 3 proposed regulations remain. For example, the 2015 edition criteria requires the capability to request patient-specific education materials in the patient's preferred language, but no requirement in Stage 3 proposed regulations require that doctors and hospitals provide education materials in non-English languages. This is a critical gap that requires further attention in order to address health disparities.

Attached are our specific comments on the template provided by ONC. We appreciate the opportunity to comment on the 2015 Edition Health IT Certification Criteria Proposed Rule. If you have any questions, please feel free to contact me or have your staff contact John DeCarlo at john.decarlo@cancer.org or 202-585-3216.

Sincerely,

Chris Hansen
President
American Cancer Society Cancer Action Network

[1] Committee on Improving the Quality of Cancer Care: Addressing the Challenges of an Aging Population; Board on Health Care Services; Institute of Medicine; Levit L, Balogh E, Nass S, et al., editors. Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis. Washington (DC): National Academies Press (US); 2013 Dec 27. 3, Patient-Centered Communication and Shared Decision Making.

§ 170.315(a)(5) Demographics

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Demographics.
(i) Enable a user to record, change, and access patient demographic data including preferred language, sex, race, ethnicity, and date of birth.
(A) Race and ethnicity.
(1) Enable each one of a patient's races to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify race.
(2) Enable each one of a patient's ethnicities to be recorded in accordance with, at a minimum, the standard specified in § 170.207(f)(2) and whether a patient declines to specify ethnicity.
(3) Aggregate each one of the patient's races and ethnicities recorded in accordance with paragraphs (a)(5)(i)(A)(1) and (2) of this section to the categories in the standard specified in § 170.207(f)(1).
(B) Enable preferred language to be recorded in accordance with the standard specified in § 170.207(g)(2) and whether a patient declines to specify a preferred language.
(C) Enable sex to be recorded in accordance with the standard specified in § 170.207(n)(1).
(ii) Inpatient setting only. Enable a user to record, change, and access the preliminary cause of death and date of death in the event of mortality.

Preamble FR Citation: 80 FR 16816 **Specific questions in preamble?** *No*

Public Comment Field:

We support the more granular race and ethnicity measure. This new criterion improves the ability of the entire learning health system to identify, understand and reduce health disparities in underserved areas that can result in decreased cancer rates.

§ 170.315(a)(10) Clinical decision support

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

Implement clinical decision support (CDS) interventions focused on improving performance on high-priority health conditions.

§ 170.315(a)(10) Clinical decision support

2015 Edition Health IT Certification Criterion

(2) Clinical decision support.

(i) Evidence-based decision support interventions. Enable a limited set of identified users to select (i.e., activate) one or more electronic clinical decision support interventions (in addition to drug-drug and drug-allergy contraindication checking) based on each one and at least one combination of the following data:

(A) Problem list;
(B) Medication list;
(C) Medication allergy list;
(D) At least one demographic specified in paragraph (a)(5)(i) of this section;
(E) Laboratory tests; and
(F) Vital signs.

(ii) Linked referential clinical decision support.

(A) Technology must be able to identify for a user diagnostic and therapeutic reference information in accordance with the standard and implementation specifications at § 170.204(b)(3) or (4).
(B) For paragraph (a)(10)(ii)(A) of this section, technology must be able to identify for a user diagnostic or therapeutic reference information based on each one and at least one combination of the data referenced in paragraphs (a)(10)(i)(A), (B), and (D) of this section.

(iii) Clinical decision support configuration.

(A) Enable interventions and reference resources specified in paragraphs (a)(10)(i) and (ii) of this section to be configured by a limited set of identified users (e.g., system administrator) based on a user's role.
(B) Technology must enable interventions to be:
(1) Based on the data referenced in paragraphs (a)(10)(i)(A) through (F) of this section.
(2) When a patient's medications, medication allergies, problems, and laboratory tests and values/results are incorporated from a transition of care/referral summary received and pursuant to paragraph (b)(2)(iii)(D) of this section.
(3) Ambulatory setting only. When a patient's laboratory tests and values/results are incorporated pursuant to paragraph (b)(4) of this section.

(iv) CDS intervention interaction. Interventions provided to a user in paragraphs (a)(10)(i) through (iii) of this section must occur when a user is interacting with technology.

(v) Source attributes. Enable a user to review the attributes as indicated for all clinical decision support resources:

(A) For evidence-based decision support interventions under paragraph (a)(10)(i) of this section:
(1) Bibliographic citation of the intervention (clinical research/guideline);
(2) Developer of the intervention (translation from clinical research/guideline);
(3) Funding source of the intervention development technical implementation; and
(4) Release and, if applicable, revision date(s) of the intervention or reference source.
(B) For linked referential clinical decision support in paragraph (a)(10)(ii) of this section and drug-drug, drug-allergy interaction checks in paragraph (a)(4) of this section, the developer of the intervention, and where clinically indicated, the bibliographic citation of the intervention (clinical research/guideline).

(vi) Intervention response documentation.

(A) Technology must be able to record at least one action taken and by whom in response to clinical decision support interventions.
(B) Technology must be able to generate either a human readable display or human readable report of actions taken and by whom in response to clinical decision support interventions.

§ 170.315(a)(10) Clinical decision support	
Preamble FR Citation: 80 FR 16820	**Specific questions in preamble?** *Yes*

Public Comment Field:

1. CDS is the primary means of applying best evidence and knowledge at the point and time of care. For this reason, we strongly support recording a CDS intervention at the point of care.
2. We commend ONC on adding resources while enabling a user to review the attributes as indicated for all clinical decision support resources.
3. We strongly recommend that CDS criterion also require requesting patient specific education resources based on preferred language.

§ 170.315(a)(12) Smoking status	
Included in 2015 Edition Base EHR Definition?	
Yes	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(3) Smoking status. Enable a user to record, change, and access the smoking status of a patient in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).	
Preamble FR Citation: 80 FR 16822	**Specific questions in preamble?** *No*

Public Comment Field:

We strongly support the criterion 170.315(a)(12) Smoking Status. In the US, an estimated 8.6 million people suffer from chronic conditions related to smoking and tobacco use is responsible for 1 in 5 deaths each year.[2] In 2014, one third of the estimated cancer deaths will be caused by tobacco use.[3] The U.S. Surgeon General issued a report finding that people, who quit, regardless of their age, live a longer and healthier life than individuals who continue to use tobacco products.[4] Research shows that tobacco use screening and cessation treatments are both clinically effective and cost-effective when compared to other disease prevention intervention and medical treatments. In fact, in a systematic assessment of preventive services, tobacco use screening and cessation treatment – including pharmacotherapy and counseling, was one of the highest ranked intervention services for effectiveness.[5]

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[2] American Cancer Society, Cancer Facts & Figures 2015.
[3] Ibid.
[4] US Department of Health and Human Services. *The Health Benefits of Smoking Cessation: A Report of the Surgeon General*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1990
[5] Coffield AB, Maciosek MV, McGinnis JM *et al*. Priorities Among Recommended Clinical Preventive Services. *Am J Prev. Med* 2001; 21(1).

§ 170.315(a)(13) Image results
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective N/A
2015 Edition Health IT Certification Criterion (4) Image results. Indicate to a user the availability of a patient's images and narrative interpretations (relating to the radiographic or other diagnostic test(s)) and enable electronic access to such images and narrative interpretations.
Preamble FR Citation: 80 FR 16822 **Specific questions in preamble?** *No*
Public Comment Field: We strongly support criterion 170.315(a)(13) Image results. Giving cancer patients the ability to access image results made available by electronic health records (EHRs) is a critical function that can help patients better understand their diagnosis, improve individual treatment adherence, and support overall care coordination by keeping the patient informed and engaged across the care continuum.

§ 170.315(a)(17) Patient-specific education resources
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective 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.
2015 Edition Health IT Certification Criterion (5) Patient-specific education resources. Technology must be able to: (i) Identify patient-specific education resources based on data included in the patient's problem list and medication list in accordance with the standard (and implementation specifications) specified in § 170.204(b)(3) or (4); and (ii) Request that patient-specific education resources be identified in accordance with the standard in § 170.207(g)(2).
Preamble FR Citation: 80 FR 16823 **Specific questions in preamble?** *No*

§ 170.315(a)(17) Patient-specific education resources

Public Comment Field:

1. We support the requirement that EHRs can request patients' specific education resources based on the patient's preferred language. Providing cancer patients and their families with understandable information about cancer diagnosis, prognosis and the benefits, harms, and costs of treatments as well as discussing patients' options, such as revisiting and implementing advance care plans, are critical elements to improve quality and patient experience of care.
2. We recommend ONC and CMS better align criteria across the 2015 Health IT certification and Stage 3 proposed regulations. While this criterion requires the capability to request patient-specific education materials in the patient's preferred language there is no requirement in Stage 3 proposed regulations that requires doctors and hospitals provide education materials in non-English languages.

§ 170.315(a)(19) Patient health information capture

Included in 2015 Edition Base EHR Definition?

No, but proposed for the EHR Incentive Programs CEHRT definition

Stage 3 MU Objective

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

(6) Patient health information capture. Technology must be able to enable a user to:
(i) Identify, record, and access patient health information documents;
(ii) Reference and link to patient health information documents; and
(iii) Record and access information directly shared by a patient.

Preamble FR Citation: 80 FR 16823 **Specific questions in preamble?** *No*

Public Comment Field:

1. We support the new "advance directives" criterion to capture patient health information documents more broadly.
2. We also support that the revised criterion now applies to any patient regardless of age, not just those age 65 and older, because the documents (e.g. birth plans) cover the lifespan.

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

Included in 2015 Edition Base EHR Definition?

No

Stage 3 MU Objective

N/A

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

2015 Edition Health IT Certification Criterion

(7) 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*

Public Comment Field:

1. We support the use of data on social determinants of health as a form of Patient Generated Health Data (PGHD) counted towards Meaningful Use Objective 6.
2. We recommend that Industry/occupation information has clinical relevance and is important to capture, particularly for underserved populations who work jobs with significant risks and environmental hazards that have implications for increased risk of developing cancer.

§ 170.315(b)(6) Data portability

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 MU Objective

N/A

§ 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:

We recommend ONC add clinical notes as part of the criterion. People with cancer often receive fragmented and uncoordinated care, as their treatments frequently require help from multiple clinicians including, surgeons, oncologists, primary care physicians, and specialists. Providing care that is coordinated requires access to all of a patient's data by all of his or her providers. Clinical notes may contain specific information about patient preferences or experiences throughout the course of treatment that can better inform clinical decision-making.

§ 170.315(b)(9) Care plan	
Included in 2015 Edition Base EHR Definition?	
No	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(2) Care plan. Technology must enable a user to record, change, access, create, and receive care plan information in accordance with the Care Plan document template in the standard adopted in § 170.205(a)(4).	
Preamble FR Citation: 80 FR 16842	**Specific questions in preamble?** *Yes*
Public Comment Field:	
1. We strongly support the new criterion that can capture a coordinated view of care across multiple sites, providers and episodes, and to integrate that with patients' health issues and treatment goals. 2. We support requiring health status evaluations and outcomes section as part of the criteria. Clinician and patient reported health outcomes data will provide the necessary information that will move us toward better quality and value in delivery system reform. 3. We support adding the interventions section and accompanying care instructions as part of an integrated care plan for both providers and individuals.	

§ 170.315(d)(4) Amendments	
Included in 2015 Edition Base EHR Definition?	
No, but a conditional certification requirement	
Stage 3 MU Objective	
N/A	
2015 Edition Health IT Certification Criterion	
(1) Amendments. Enable a user to select the record affected by a patient's request for amendment and perform the capabilities specified in paragraph (d)(4)(i) or (ii) of this section. (i) Accepted amendment. For an accepted amendment, append the amendment to the affected record or include a link that indicates the amendment's location. (ii) Denied amendment. For a denied amendment, at a minimum, append the request and denial of the request to the affected record or include a link that indicates this information's location.	
Preamble FR Citation: 80 FR 16847	**Specific questions in preamble?** *No*
Public Comment Field:	
In addition to the 2014 edition, which enables providers to accept or deny request amendments, and append it to patient's record, we recommend CEHRT must be able to maintain the provenance of amendments and other patient-generated health data (PGHD).	

§ 170.315(e)(1) View, download, and transmit to a third party
Included in 2015 Edition Base EHR Definition? No
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(e)(1) View, download, and transmit to a third party

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).

(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

§ 170.315(e)(1) View, download, and transmit to a third party

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*

Public Comment Field:

1. We appreciate ONC's continued attention to make it clear that VDT is patient-facing and for patients to use, and specific reference to authorized representatives.
2. We support making additional data available to patients, such as diagnostic images, as well as "transitions of care" and "care plans" that are essential to view for coordination of care.
3. We support the ability to select information for viewing and downloading based on specific data or time, or period of time.
4. We recommend CMS and ONC work with the appropriate federal agencies to develop and publish guidance for app developers to assure adherence to appropriate privacy and security protections for protected health information.

§ 170.315(e)(2) Secure messaging
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective 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 (2) Secure messaging. Enable a user to send messages to, and receive messages from, a patient in a manner that ensures: (i) Both the patient (or authorized representative) and technology user are authenticated; and (ii) The message content is encrypted and integrity-protected in accordance with the standard for encryption and hashing algorithms specified at § 170.210(f).
Preamble FR Citation: 80 FR 16850 **Specific questions in preamble?** *No*
Public Comment Field: We recommend EHR technology be capable of tracking the response to a patient-generated message (e.g., no response, secure message reply, telephone reply). Sending secure messages to patients or clinicians without knowing whether it was received runs counterintuitive to the communication process. In this case, the communication process relies on both the sending and receiving of messages to be effective and should be recorded as such.

§ 170.315(f)(4) Transmission to cancer registries
Included in 2015 Edition Base EHR Definition? No
Stage 3 MU Objective The EP, eligible hospital, or CAH is in active engagement with a PHA or CDR to submit electronic public health data in a meaningful way using certified EHR technology, except where prohibited, and in accordance with applicable law and practice.
2015 Edition Health IT Certification Criterion (1) Transmission to cancer registries. Technology must be able to create cancer case information for electronic transmission in accordance with: (i) The standard (and applicable implementation specifications) specified in § 170.205(i)(2); and (ii) At a minimum, the versions of the standards specified in § 170.207(a)(4) and (c)(3).
Preamble FR Citation: 80 FR 16854 **Specific questions in preamble?** *Yes*
Public Comment Field: We strongly support criterion 170.315(f)(4). Accurate and detailed cancer information enables better public policy development by allowing more detailed analysis and tracking of cancer rates and trends over time and across the US population. This has significant implications for public health interventions targeting specific geographic areas or populations with high rates of cancer.

§ 170.315(g)(7) Application access to Common Clinical Data Set
Included in 2015 Edition Base EHR Definition? Yes
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) 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.
Preamble FR Citation: 80 FR 16860 **Specific questions in preamble?** *Yes*

§ 170.315(g)(7) Application access to Common Clinical Data Set
Public Comment
1. We strongly support patient facing Application Program Interface (API) access that allows patients to share health information as desired with tools, applications and platforms of their choosing. 2. We suggest that to ensure a truly public and open API, documentation must be publicly available and free to developers. 3. We recommend CMS and ONC work with the appropriate federal agencies to develop and publish guidance for app developers to assure adherence to appropriate privacy and security protections for protected health information.

Common Clinical Data Set Definition	
Preamble FR Citation: 80 FR 16871	**Specific questions in preamble?** *No*
Public Comment Field:	
1. We strongly support the inclusion of smoking status in the definition. In the US, an estimated 8.6 million people suffer from chronic conditions related to smoking and tobacco use is responsible for 1 in 5 deaths each year.[6] In 2014, one third of the estimated cancer deaths will be caused by tobacco use.[7] The U.S. Surgeon General issued a report finding that people, who quit, regardless of their age, live a longer and healthier life than individuals who continue to use tobacco products.[8] Research shows that tobacco use screening and cessation treatments are both clinically effective and cost-effective when compared to other disease prevention intervention and medical treatments. In fact, in a systematic assessment of preventive services, tobacco use screening and cessation treatment – including pharmacotherapy and counseling, was one of the highest ranked intervention services for effectiveness.[9] 2. We recommend sexual orientation and gender identity also is included within this definition given the variability of cancer screenings and exams among transgendered individuals and lesbian or bisexual women.[10]	

[6] American Cancer Society, Cancer Facts & Figures 2015.
[7] Ibid.
[8] US Department of Health and Human Services. *The Health Benefits of Smoking Cessation: A Report of the Surgeon General*. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 1990
[9] Coffield AB, Maciosek MV, McGinnis JM *et al*. Priorities Among Recommended Clinical Preventive Services. *Am J Prev. Med* 2001; 21(1).
[10] The Fenway Institute & Center for American Progress, Asking patients questions about sexual orientation and gender identity in clinical settings: A study in four health centers (2013), available at http://thefenwayinstitute.org/wp-content/uploads/COM228_SOGI_CHARN_WhitePaper.pdf.