May 29, 2015

Submitted electronically

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Suite 729D
Washington, D.C. 20201

Attn: 2015 Edition HER Standards and Certification Criteria Proposed Rule

Re: Healthwise and Informed Medical Decisions Foundation

Dear Dr. DeSalvo:

Healthwise, a 40-year-old nonprofit, has had a consistent mission to help people make better health decisions. People have turned to our content over 1.5 billion times on the web, in print, via mobile devices, in care via patient-specific education, in personal health records, and in population health tools. In 2014 Healthwise recommitted to our mission through merging with the Informed Medical Decisions Foundation. Together our combined organizations deepen our mission and our commitment to the people we serve.

These proposed regulations are a very important step in the effort to ensure that health IT facilitates better care, better health, and better value, and that they clearly reflect a commitment to meeting the needs of patients and families. Collectively, the regulations make great strides in advancing the technological capacity to support patients across the continuum of care. By reaching beyond certified EHRs for the Meaningful Use program to address health IT broadly, they extend the benefits to patients and families in long-term and post-acute care settings, in behavioral health settings, and in pediatric settings. They facilitate the movement toward patient-centered care through capture of critical information about individuals' health and care outside the clinical setting (for example, patients' goals and care team members in the Common Clinical Data Set, social determinants of health, health information documents such as birth plans and advance directives, etc.). Indeed, the NPRM contains a number of recommendations that are consistent with our mission to help people make better health decisions. The reader is sometimes left wishing that the important new capability could be paired with a complementary policy requirement that providers use it meaningfully to benefit all patients—for example, the 2015 edition includes the capability to request patient-specific education materials in the patient's preferred language, but there is no requirement in the proposed regulations for Stage 3 that doctors and hospitals provide education materials in non-English languages.

How ONC defines and augments the 2015 edition criteria matters, and it affects individuals, patients, family caregivers, and communities across America. Defining "Care Plans" criteria 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.

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§ 170.102—Common Clinical Data Set

Healthwise and IMDF appreciate ONC's work here to define the common set of clinical data for certified EHR technology and health IT. We greatly appreciate and support the inclusion of assessment and plan of treatment, goals, health concerns, and care team members in this data set because these data are critical pieces of information for care and for safe and effective transitions of care. For example, goals (in the C-CDA, release 2.0. "Goals Section") include patient-defined overarching goals, and health concerns (in the "Health Concerns Section") include health-related matters of interest, importance, or worry to someone, such as the patient, the patient's family, or the patient's provider. We commend the inclusion of patient-articulated goals and concerns along with clinical goals and concerns, both of which are essential for shared decision making.

While the Common Clinical Data Set includes care team members, the NPRM is silent about the definition of care team members. We encourage ONC to define care team members with similar reference to the C-CDA, release 2.0, where the "Care Plan Section" provides that care team members include patients, their caregivers, and their providers, and the "US Realm Header" template for the "Patient Generated Document" lists the range of personal caregivers. Likewise, the draft Interoperability Roadmap included "Notes/narrative" in the common clinical data set there, but the NPRM neglects to include that in the Common Clinical Data Set here. We encourage the use of these standards and call for additional work in a common vocabulary to be used in all patient-generated data, especially data used in common questionnaire information sought from the patient. Current work in SNOMED can inform this vocabulary. The initial consumer vocabulary and taxonomy uses synonyms of medical terms reflected in consumer and plain language as a result of years of work and use in the field by Kaiser Permanente.

Preferred language

We strongly support recording all languages preferred by the patient. Identification and use of a patient's preferred language, whatever it is, enables providers to improve care and better support patients by providing them meaningful information in languages they understand and use, thereby improving patient safety and care quality.

§ 170.315(a)(10)-Clinical Decision Support (CDS)

We support the proposal to record the action taken with regard to CDS without impeding workflow—for example, whether the provider viewed, accepted, declined, ignored, or provided an explanation for another action taken. Given the importance of clinical decision support, it makes good sense.

We agree that this criterion should also include the capability for patients to be part of the decision-making team, that clinical decision support is a primary means of providing best evidence and knowledge at the point and time of care, and that this is the prime moment to include patients in shared decision making.

We are concerned that the recommended standards do not include the patient in the design, but we applaud a common query approach with patient-specific education materials (Infobutton standard). We recommend that (with the exception of the Infobutton standard for query) ONC not adopt standards for CDS. In order to promote responsible innovation by CDS developers, we encourage ONC to consider a certification of CDS developers only, and that the content certification be considered outside the domain of HIT. We recommend emphasis in HIT be that of the query and response of the CDS to the HIT system and that these data standards include the patient in their design.

*§ **170.315(a)(17)-Patient-Specific Education Resources***

We fully support leveraging health IT to identify and provide access to meaningful patient-specific education resources by requiring health IT to request these resources based on preferred language. This requirement helps to ensure that every patient can understand relevant information for better care and better health. Furthermore, making education resources available in the patient's preferred language is directly aligned with the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, the HHS Action Plan to Reduce Racial and Ethnic Health Disparities, and the National Stakeholder Strategy for Achieving Health Equity.

For these reasons, though, the capability to *request* resources in the patient's language is necessary but insufficient: EHRs and health IT must be able to *provide* the resources in the patient's language for most patients. According to the Census Bureau, more than 37 million Americans (ages 5 and older) spoke Spanish at home in 2011. More than 60 million, or 21%, of Americans spoke some language other than English at home. EHRs should be able to provide 100% of education resources in English and Spanish. When ONC raised this question in its Voluntary 2015 Edition NPRM, developers did not support a proposal to provide all resources in all preferred languages because of the unintended consequences that development burden would have on reducing the amount of resources available to the English- and Spanish-speaking populations. Providing all the resources in English and Spanish plus a basic set of selected resources in the top five national languages would address that concern.

*§ **170.315(a)(19)-Patient Health Information Capture***

We appreciate and strongly support ONC's proposed expansion of this criterion to capture multiple types of information that record the individuals' and patients' care preferences, from birth plans to advance directives. This necessarily broadens the age range, as well as patient health information documents, since birth plans occur much earlier than age 65.

We also support ONC's proposal to make this criterion much more useful by adding the capability to store and access the document and to include information on where to locate it; for example, by link to the document or instructions about where to find it.

The specifics of documents such as birth plans and advance directives constitute essential patient preference information that is necessary for providers to act with consideration of their patients' choices. Patients and providers benefit significantly from having the *content* of such documents available at the point and time of care. A bipartisan letter from eight members of the U.S. House of Representatives made similar suggestions in calling on ONC and CMS to advance care planning, including the advance directive objective, in the third stage of Meaningful Use.

Improving End-of-Life Care

Facing death is a profound challenge for people, their relatives and friends, their caregivers, and healthcare institutions. Advance care planning supports patients and families in discussing and documenting care preferences, with the goal of ensuring that the care patients receive is aligned with their goals, values, and preferences. People use advance care planning documents to aid in determining the type of care they want if they cannot speak for themselves.

Advance care planning encompasses the entire process of discussion regarding end-of-life care, clarification of related values and goals, and the expression of preferences through written documents and medical orders. Documents in advance care planning may include an advance directive such as a living will or a durable power of attorney for health care. Individuals can complete these forms at any time and in any state of health. Other advance care planning documents contain a medical order signed by a health professional, which

includes Physician Orders for Life-Sustaining Treatment (POLST)[1] or do-not-resuscitate, do-not-intubate, do-not hospitalize orders, documents that cover specific treatments and are more likely to be completed as health deteriorates.[2]

Advance care planning is about honoring a patient's choice rather than making decisions for them. Research shows that advance care planning significantly improves outcomes of care including increased compliance with patient preferences, fewer hospitalizations, and less intensive treatments.[3,4] Both the Centers for Disease Control and Prevention (CDC)[5] and the Institute of Medicine (IOM) have advocated for increased use of advance care planning.

The Institute of Medicine's recent report, *Dying in America*, specifically called for:

> *"the use of interoperable electronic health records that incorporate advance care planning to improve communication of individuals' wishes across time, settings, and providers, documenting (1) the designation of a surrogate/decision maker, (2) patient values and beliefs and goals for care, (3) the presence of an advance directive, and (4) the presence of medical orders for life-sustaining treatment for appropriate populations."*[6]

Capturing an advance care plan in EHRs is crucial when patients are not able to express their own preferences. According to the recent Institute of Medicine (IOM) report, "*Dying in America*: *Improving Quality and Honoring Individual Preferences Near the End of Life*," an estimated 40% of all adults in inpatient settings are unable to make their own treatment decisions due to illness. Among those aged 60 and older, that number increases to 70%.

Stage 1 and Stage 2 of Meaningful Use took a vital first step in recognizing the critical role of EHRs in advance care planning by ensuring that EHRs could document whether a patient had an advance directive. The proposed Stage 3 rule takes a significant step forward by including a provision that requires EHRs be able to store a patient's advance directive or provide a link to an external location where the document resides. There are, however, significant opportunities to further support advance care planning, including facilitating the transmission of advance care plans across sites of care in Stage 3. We are hopeful that the proposed rules for Meaningful Use can be modified to better encourage advance care planning and the sharing of plans.

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[1] Physician Orders for Life-Sustaining Treatment (POLST) paradigm is an approach to end-of-life planning based on conversations between patients, loved ones, and health care professionals designed to ensure that seriously ill or frail patients can choose the treatments they want or do not want and that their wishes are documented and honored.

[2] *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life* (2014). Consensus report. Washington, D.C.: Institute of Medicine. www.iom.edu/endoflife.

[3] Teno JM, Gruneir A, Schwartz Z, Nanda A, Wetle T. (2007). Association between advance directives and quality of end-of-life care: A national study. *Journal of the American Geriatrics Society,* 55(2): 189-194.

[4] Detering KM, Hancock AD, Reade MC, Silvester W. (2010). The impact of advance care planning on end of life care in elderly patients: Randomised controlled trial. *BMJ.* 340: c1345; Hammes BJ, Rooney BL. (1998). Death and end-of-life planning in one midwestern community. *Archives of Internal Medicine.* 158(4): 383-390.

[5] CDC's Healthy Aging Program, Give Peace of Mind: Advance Care Planning (March 3, 2014). www.cdc.gov/aging/advancecareplanning/.

[6] *Dying in America: Improving Quality and Honoring Individual Preferences Near the End of Life* (2014). Consensus report. Washington, D.C.: Institute of Medicine. www.iom.edu/endoflife.

Comments on EHR Certification Criteria

We are encouraged by ONC's proposal to adopt a new 2015 Edition certification criterion that would require an EHR to be capable of storing a patient's health information documents. The ONC specifically references an advance directive as a type of document that EHRs must be able to store. The certification criteria also state that the EHR must be able to link to an external site where a document such as an advance directive is stored or provide narrative information on where the document may be found. We strongly support this provision and suggest that this not be limited to links only, but that patient-generated data may come in several forms, to include secure email, patient portals, patient apps, and HIT modules.

The certification criteria discuss how EHRs must properly label health information documents; we strongly agree with this requirement. One challenge is that, as discussed above, there are many types of advance care plans, including living wills, durable power of attorney forms, and POLST forms. We believe that it is extremely important to use the same label—"advance care plan"—in the EHR to describe all of these types of documents. If the same consistent label is not used, it may be difficult for providers to search for and find forms that may be highly relevant in the end-of-life context. Therefore, we urge ONC to clarify that the term "advance care plan" should be used to refer to all of these types of documents.

The recommendations made by the HITSC Consumer Engagement Team recommended the use of the CCDA patient-generated header, with specific use cases identified that would support POLST, MOLST, and many forms of AD. We encourage review of these recommendations and of the current work of HL7 CCDA version 2, including a care team roster and questionnaire structure, which could further inform this effort.

While it is important to capture, store, and link to a plan, there is a significant opportunity to improve advance care planning through accessibility across care settings. Transitions in care from one site to another, or from one specialist to another, can often disrupt the continuity of the treatment. A study in the *Journal of Palliative Medicine* found that as very sick patients were transferred between several care settings, the likelihood that advance care plan information was available in new settings was "no greater than chance."[7] In addition, a recent study in the *Journal of the American Medical Association* found that people face an average of 3.1 transitions between different care sites in their final 3 months of life.[8]

To solve this lack of continuity of treatment, we believe that any document labeled as an advance care plan should be transmitted as part of the summary of care plan under the CCDS (§ 170.102). We see two potential options to ensure that documents labeled as advance care plans are part of the CCDS. The first is to include these documents as a new element in the CCDS labeled "Advance Care Plan." The second option is to include advance care plans in an existing element in the CCDS, such as the care plan, which is described in the ONC proposed rules as the "…assessment, plan of treatment, goals, and health concerns for the patient." A robust care plan would include an advance care plan to capture essential patient preferences and goals of care. And unlike other forms of patient-generated health data, such as birth plans and fitness information, even the healthiest people may need access to their advance care plan of treatment at any time. We urge ONC to make this change to the CCDS in the final rule.

Additionally, we recommend that the "View, Download, and Transmit" function for patients include access to the advance directive of record. In this way the patient can view the current advance directive, establish version accuracy, and transmit to other providers. When new versions are needed, the ability for patients to request an amendment to their record via secure email or other methods and to attach the current version is key to providing accurate and current advance directives.

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[7] Yung, VY, Walling AM , Min L, Wenger NS, Ganz DA. (2010). Documentation of advance care planning for community-dwelling elders. *Journal of Palliative Medicine* 13(7): 861–867.

[8] Teno JM, Gozalo PL, Bynum JW, et al. (2013). Change in end-of-life care for Medicare beneficiaries: Site of death, place of care, and health care transitions in 2000, 2005, and 2009. *JAMA*.309(5): 470-477. doi:10.1001/jama.2012.207624.

Unique Device Identification: UDI

Given the recognized value of UDI capture in EHRs, the Health Information Technology Policy Committee—a federal advisory panel—approved recommendations to create a Meaningful Use Stage 3 objective to record the UDI of implanted devices at the time of implantation.

As part of the Meaningful Use Stage 3 proposed rule, CMS underscores the importance of health information exchange among providers. The proposed CMS objective would offer financial incentives for providers and hospitals to obtain summary-of-care information on patients treated by another provider, transmit summary-of-care data to other providers, and reconcile the information from another provider when encountering a new patient. This summary-of-care information would be the transmission of the CCDS, which includes the UDI of implanted devices.

We support this provision for both eligible providers and hospitals to ensure that UDI data is exchanged among clinicians and facilities caring for patients with implanted devices. As patients' implanted devices are essential features of their medical history, exchanging UDI among providers and hospitals is integral to ensuring high-quality care. Primary care physicians, specialists, and other providers must receive the list of devices implanted in their patients to identify individuals in the event of a recall, to support care coordination among clinicians, and to ensure that doctors have a complete medical history to answer patients' questions.

We strongly support this objective to facilitate the exchange of critical patient information—particularly the UDIs of implanted devices—through the transmission and receipt of the CCDS. While CMS indicates that summary-of-care documents are expected to "contain the most recent and up-to-date information on all elements," CMS should clarify that this requires the documentation of the UDIs of implanted devices at the time of the procedure.

Both ONC and CMS have underscored the importance of patient and physician access to accurate information on the devices implanted. Those implanted devices are a critical component of the patient's health history and must be documented and exchanged among patients, primary care physicians, and specialists.

By allowing physicians and patients to know which devices are implanted and used in care, the UDI system has the potential to facilitate recalls, improve clinical decision support, and enhance the data available on medical device performance—but only once incorporated into electronic health information, including patients' medical records and insurance claims, which will provide better longitudinal data on patient outcomes.

The development of EHR certification criteria and a Meaningful Use objective to support UDI capture; the patients' ability to view, download and transmit this information; and the transmission by all stakeholders are critical next steps to achieve those benefits.

§ 170.315(b)(1)-Transitions of Care

We appreciate and support ONC's proposal to adopt the updated Consolidated CDA (C-CDA) standard when providing summary-of-care records for transitions of care or referrals, and to include the Common Clinical Data Set. The updated C-CDA includes the structural elements for care plans, patient goals, and health outcomes that are important to consumers' vision of longitudinal, bi-directional health and care planning.

Patients receiving transitions-of-care or summary-of-care documents electronically in care or via online services (VDT) should include the ability to link to patient-specific education resources consistent with current EHR functionality and standards. (infoButton)

§ 170.315(b)(9)-Care Plans

We strongly support this new criterion and its potential to capture for providers, patients, and family caregivers a coordinated view of care across multiple sites, providers, and episodes, and to integrate that with patients' currently active health issues and future goals and expectations. The "Care Plan" template in the Consolidated CDA, release 2.0, includes patient-articulated goals and concerns along with clinical goals and concerns, both of which are essential for shared decision making. It reflects the full range of care team members, including the patient, the patient's family, and the patient's providers. These are the structural elements that are important to consumers' vision of longitudinal, bi-directional health and care planning.

We recommend including the "Health Status Evaluations and Outcomes Section" and "Interventions Section (V2)." The first template captures outcomes of care from the interventions used to treat the patient in relation to the care plan goals. This is precisely the patient-reported and clinician-reported outcomes data we need for more sophisticated quality and value measurement and delivery system reform. The second template and accompanying care instructions section would be especially useful for patients and family caregivers. We recommend ONC continue to refine this work through the development and support of a consumer taxonomy and vocabulary for patient goals, and common patient-generated data used in care planning.

These are care plan elements that patients across the country want and would use. In a nationally representative survey conducted by the National Partnership for Women & Families and released in December 2014, the majority of patients (56%) stated that they wanted to review doctors' treatment recommendations and care plans. Half set or track goals for their health all or most of the time.

§ 170.315(d)(2)-Auditable Events and Tamper-Resistance

We recommend that the final 2015 certification criteria include the requirement ONC proposed in the Voluntary 2015 Edition NPRM, that EHR technology include tamper resistance technology to support patient transmittal of their records in a way that provides the confidence necessary to all parties that the data is sound and the sources unquestionable, even when transmitting on behalf of other parties. For example, patients may be transmitting data from one provider to another in order to coordinate care, or patients may be providing data from a device or health app of their choice. In all cases, provenance and tamper-proof seals are important to make the data actionable and trusted.

§ 170.315(d)(4)-Amendments

Amendments are an important form of patient-generated health data (PGHD). Increased access by individuals to their own health information will potentially increase the number of errors identified and corrected by patients, thereby underscoring the need for this capability. Health IT modules must be able to maintain the provenance of this and other PGHD, and ONC should ensure that the 2015 Edition adds any specifications necessary to include this functionality (provenance).

We also recommend that the "View, Download, and Transmit" function make transitions of care, referral summaries, and care plans available to the patient and authorized representatives. Some of it will be available through the Common Clinical Data Set, but the complete information, organized as care plans and as individual transitions of care and referral summaries, is essential to view for patients' and family caregivers' understanding and coordination of care. Patient-specific education resources should also be available anytime patients view or download their record.

§ 170.315(e)(2)-Secure Messaging

In the National Partnership for Women & Families' recent survey, a majority of patients nationwide (56%) wanted the ability to email their providers. This criterion is important to America's patients and families, and we encourage ONC to improve it further. Health IT should be capable of tracking the response to a patient-generated message (for example, no response, secure message reply, telephone reply).

§ 170.315(e)(1)(iii), (g)(7)-Application Access to Common Clinical Data Set

Healthwise agrees with ONC that patient-facing application programming interface (API) access is a valuable capability separate from clinician- facing access, and the NPRM rightfully calls this out as its own certification criterion. The requirement and testing of APIs, however, need to go beyond their ability to respond to requests for patient data from other applications; they must ensure as well that all functionalities required in the "View, Download, and Transmit to Third Party function are equally available through the API—for example, view, download, transmit patient-generated health data, and secure messaging.

In addition, access to the Common Clinical Data Set is not enough. For example, as proposed, the Common Clinical Data Set includes the plan of care for a single provider and encounter, but it does not include the synthesis of multiple plans of care set forth in the "Care Plans" criterion, which would be equally important to patients and their authorized representatives. Similarly, the Common Clinical Data Set does not include items such as referral summaries, discharge instructions, and documents listed in the Patient Health Information Capture criterion, such as birth plans and advanced directives.

§ 170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE

There is strong support for patient-generated data: medication history to be gathered and placed into the medical record. Drug interaction checkers should include this patient-generated information for the provider to consider.

§ 170.315(a)(7) Problem list

The problems list often originates with the patient's complaint or reason for a visit, and it is an ideal application for patient-generated data electronically (PGHD) and a logical place for the use of consumer taxonomy and vocabulary.

§ 170.315(a)(8) Medication list

There is strong support for patient-generated data: medication history and medication adherence should be gathered and placed into the medical record. The use of standardized questionnaires (HL7 CCDA patient generated header) can provide a standards-based approach. PGHD should be encouraged in this objective.

§ 170.315(a)(9) Medication allergy list

There is strong support for patient-generated data: Allergies to be gathered and placed into the medical record. The use of standardized questionnaires (HL7 CCDA patient-generated header) can provide a standards-based approach. PGHD should be encouraged in this objective.

§ 170.315(a)(10) Clinical Decision Support

CDS should include the patient's values and goals of care in order for the provider and patient to make the most informed decision. CDS that includes the patient is most often called shared decision making (SDM). SDM includes electronic tools that gather patient values, leanings, and preferences and that promote discussion between the provider and the patient. We applaud the harmonization of the query standards with the current information retrieval (HL7 infoButton standard) which is used today in the millions monthly to retrieve medical journals, articles, and patient-specific education. API standards could be enhanced to reflect

the Infobutton context and aligned with the Common Clinical data set, to include patient health information retrieval. An example of this use case could be advance directives and patient-generated histories, goals of care, values, and direction.

Certification of CDS/SDM content providers should be considered in current certification specifications and therefore should be reviewed and reconstructed in that light, as the recommended standards do not support the patient as a decision maker.

§ 170.315(a)(11) Drug-formulary and preferred drug list checks

Cost data for medications can help providers and patients determine the best solution for each patient encounter. Using a model similar to the pharmacy benefits management interface that allows for real-time access to cost and formulary data to the provider in the care workflow and to the patient in the portal workflow can help with shared decision making between the provider and the patient. Encourage the use of medication cost information both for the provider and the patient.

§ 170.315(a)(12) Smoking status

Encourage the use of PGHD questionnaires for information in care and updates as the patient's smoking status changes.

§ 170.315(a)(13) Image results

Access should include the patient's ability to view, download, and transmit. Additionally as a patient VDTs this data, this data (radiology report) should be tied to patient-specific education materials, so that every digital access is an informed access (HL7 Infobutton standard).

§ 170.315(a)(14) Family health history

Family health history originates with the patient and is an ideal application for patient-generated data electronically (PGHD). Patients' ability to self-identify their familial concepts will provide accurate information and more patient engagement.

§ ***170.315(a)(15) Family health history*** – pedigree

Family health history originates with the patient and is an ideal application for patient-generated data electronically (PGHD). Patients' ability to self-identify their pedigree will provide accurate information and more patient engagement.

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

In addition to PSER available to the provider in the EMR via the Infobutton, all VDT accessed through an API, portal, or tethered portal should accommodate the ability to link to (via Infobutton), or download with the record, patient-specific education materials.

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

External sources may include the patient's app of choice (ONC ACB certified required) or an attachment to a secure email, or commercially available products where the patient has granted access. This work can support advance directives, family health histories, and other PGHD, for example, health risk assessments and shared decision making.

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

The patient is the source of the majority of this data, and therefore PGHD should be considered. And as patients begin to self-identify their readiness for care and support, both the provider and the patient description of this readiness should be aligned in a common taxonomy/vocabulary.

§ 170.315(a)(22) Decision support – knowledge artifact

Clinical decision support in the best sense includes the patient in the process. This shared decision making with patients will include patient-generated data that give the provider important information on the patient's decision, leanings, and values. Measures should accommodate the patient as a participant in CDS. We applaud the harmonization of the query standards (Infobutton) for both patient-specific education and CDS, and we hope that this harmonization will continue with the proposed API structure. However, recommended standards do not include the patient in design and should not be considered as mature or complete enough to support CDS and SDM.

§ 170.315(a)(23) Decision support – service

Clinical decision support in the best sense includes the patient in the process. This shared decision making with patients will include patient-generated data that gives the provider important information on the patient's decision, leanings, and values. Measures should accommodate patients as participants in CDS. We applaud the harmonization of the query standards (Infobutton) for both patient-specific education and CDS, and we hope that this harmonization will continue with the proposed API structure. However, recommended standards do not include the patient in design and should not be considered as mature or complete enough to support CDS and SDM.

§ 170.315(b)(2) Clinical information reconciliation and incorporation

Providers, patients, hospitals, and care team members will all be participating in electronic health records and care plans. Reconciliation is an important part of making this information sharing effective. However, as data becomes more subjective and as care teams expand to include patients and their support, the curation of subjective data may become as important as the reconciliation of quantifiable data. Different points of view warrant consideration and inclusion in care, and in fact the differences of opinion can bring rich discussion to the care plan. We encourage the continuation of reconciliation for quantifiable data, but we ask that when considering future measures and standards, patient participation and the inclusion of qualitative and subjective data be inserted into care planning. Reconciliation may not be the best approach. The curation of the data should be the principal driver in design.

Healthwise appreciates the transparent and inclusive process of the Federal Advisory Committees and the NPRM itself, and we are honored to participate in the Health Information Technology Standards and Health Information Technology Policy: Patient Empowerment Committees. The commitment to the patient and to engagement in general that ONC has demonstrated is a force for change.

Thank you,

Don Kemper
Founder, CEO

Leslie Kelly Hall
Senior Vice President Policy

Attachment:

Topic	2015 edition of Certified Health IT Module	CPeH Comments
Common Clinical Data Set 170.102	• Common Clinical Data Set—required data that must be exchanged in transitions of care (Summaries of Care) and available for patient online access through View, Download, Transmit (VDT)/Application Program Interfaces (API) • Includes: name, sex, date of birth, race, ethnicity, preferred language, smoking status, problems, meds, med allergies, lab tests, lab values, vital signs, assessment/plan of treatment, goals, health concerns, procedures, care team members, immunizations, unique device identifier (UDI) for implantable devices. • Assessment/plan of treatment, goals and health concerns are limited to providers' single encounter with patient, not entire care plan	• Support: inclusion of assessment/plan of treatment, goals, health concerns ○ Support: includes patient goals and health concerns as well as clinical goals and health concerns (C-CDA release 2.0, goals section, health concerns section)

Demographics
 	
170.315(a)(5)
	• Includes sex, race & ethnicity, preferred language, date of birth, date of death/cause of death (inpatient setting only)
	
	Race & Ethnicity:
	• Health IT Module must be capable of recording each one of a patient's races and ethnicities in accordance with CDC's race & ethnicity code system
	  • CDC standard is current equivalent of 2009 IOM standard, more granular than HHS/census standard
	  • Can be "rolled-up" into the minimum OMB standard
	• Criterion requires that CEHRT have the capability to use CDC standard, but silent on how providers interface with it and and whether they use it.
	• Both CDC and OMB standards would be included in Common Clinical Data Set.
	
	Preferred language:
	• Adopts new standard for recording preferred language (RFC 5646)
	  • supports written, spoken and signed languages and dialects
	  • current best practice; most commonly used on web
	• Would be included in Common Clinical Data Set.
	• Silent on how providers should use (e.g. drop-down box of all languages); expectation that vendors and providers collaborate to tailor implementation to patient
		Preferred language:
		• Support: We strongly support ONC's goal to include in the EHR all languages preferred by the patient
		• Amend: Understand why the regulation would be silent on *how* providers must use the criterion, e.g. CEHRT need not include a drop-down menu of languages, but should not be silent on *whether* providers use the function.

Topic	2015 edition of Certified Health IT Module	CPeH Comments
	population/clinical setting	
Patient-Specific Education Resources 170.315(a)(17)	• Must be able to *request* patient-specific education resources based on patient's preferred language identified (using Infobutton) in accordance with RFC 5646. • No longer requires electronic identification of resources based on lab values/results	• Support: Requirement that EHRs can request patient-specific education resources based on the patient's preferred language. • Amend: EHRs should be able to provide 100 percent of education resources in Spanish if not the top five languages nationally. [See ONC's related request for comment under the Clinical Decision Support criterion below, whether CDS should also be able to request resources based on a patient's preferred language.]

Care Plans
 	
170.315(b)(9)
	• **NEW:** Requires the ability to enable a user to record, change, access, create, and receive care plan information in accordance with the ''Care Plan document template'' in the C–CDA Release 2.0 standard.
	  ○ documents patient's and providers' goals, family and clinical caregivers health concerns, health status evaluations and outcomes, and interventions.
	• Represents synthesis of multiple plans of care for a patient, not just a plan of care of one provider for one episode
		• Support: Strongly support this new criterion and its potential to capture for providers, patients, and family caregivers a coordinated view of care across multiple sites, providers and episodes, and to integrate that with patients' currently active health issues and future goals and expectations.
		
		ONC solicits comment on:
		• If optional ''sections'' of Care Plan document template (e.g. health status evaluations/outcomes; interventions) should be required for certification. (Goals section and health concerns section are required.)
		  ○ Comment: Support requiring health status evaluations and outcomes section. This is precisely the patient-reported and clinician-reported outcomes data we need for more sophisticated quality and value measurement and delivery system reform.
		  ○ Comment: The interventions section and accompanying care instructions would be useful part of an integrated "care plan" for both providers and individuals.

Patient Health Information Capture (including **Advance Directives**) 170.315(a)(19)	• **NEW:** Replaces the "advance directives" criterion to capture patient health information documents more broadly, such as advance directives, birth plans, etc. • Need to be able to demonstrate that it could enable a user to record (capture and store) and access (ability to examine or review) health information documents.	• Support: includes content of/way to access advance directives; broadens to other health information documents • Interpretation: 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.
Transitions of Care 170.315(b)(1)	**ToC:** A provider who transfers or refers a patient to another setting of care or provider of care should provide a summary care record for each transition of care or referral. • Adopts updated CCDA 2.0 ○ New templates for Care Plan; Referral Note; Transfer Summary	• Support: Transition to updated CCDA because of new structural elements for care plans, patient goals, and health outcomes **Patient matching:** • Comment: Characteristics do not work equally well across the diversity of patient populations, so ONC should not only standardize individual

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	○ New sections for Goals; Health Concerns; Health Status Evaluation/Outcomes; Mental Status; Functional Status; Nutrition; Physical Findings of Skin. **Patient matching:** • Proposed standardized data include first name, last name, middle name or initial, suffix, date of birth, place of birth, maiden name, phone number, and sex. • "Sex" renamed "administrative gender"	characteristics but choose the set or combination of patient matching standards that works best across the range of patient populations, taking into account ethnic and cultural differences. • Amend: Because of the realities of gender identity, should use HL7 Version 3 "Natal Sex" measure rather than AHRQ "Administrative Gender" measure to capture sex. ○ "Sex" should be renamed "sex assigned at birth"/ "natal sex" to accurately reflect data (sex may change over course of lifetime)
Implantable Device List: **Unique Device Identifiers** (UDIs) 170.315(a)(20)	• **NEW:** ability to record, change, and access a list of UDIs corresponding to patient's implantable devices • Able to parse device identifier, batch/lot number, expiration date, production date, serial number. • Included in Common Clinical Data Set	• Support: Support this first step toward using health IT to track device implantation and outcomes, enhance patient knowledge and use of implanted devices, facilitate device recalls, prevent device-related adverse events, improve patient safety, etc. • (Revised) Amend: Include automatic identification and data capture (AIDC) to record the UDI and reduce error. Consider how best to access and integrate data beyond the "Device Description" (e.g. MRI-compatibility) which are likewise important for preventing adverse medical errors/events.
View, Download, and Transmit to Third Party (VDT) 170.315(e)(1)	• Explicit recognition, inclusion of authorized representatives (caregivers) • Uses updated CCDA 2.0 and Common Clinical Data Set • Must make diagnostic images available to patients. • Must provide lab results in accordance with CLIA • WCAG: Plan to stay at WCAG 2.0 Level A accessibility conformance requirement for *View* capability • Covers mobile access • Requires ONC-ACBs to submit a hyperlink to access the API's documentation and terms of use.	• Support: 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. • Support: Including updated CCDA (for new fields in Common Clinical Data Set), and diagnostic image reports *ONC seeks comment on:* • Should additional data, such as on encounter diagnoses, cognitive status, functional status, etc., be made available to patients? ○ Testing or certification of this additional patient data ○ Comment: Support making additional data available to patients, particularly functional status. ▪ "Transitions of care" and "care plan" information are essential to view for coordination of care. ▪ (NEW) Patient-specific education resources. • Ability to select information for viewing/downloading based on specific data or time, or period of time ○ Support.
VDT-Application	• **NEW:** Capability to handle requests for patient data from	• Support: Patient-facing API access is a valuable capability separate from

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Access to Common Clinical Data Set 170.315(e)(1)(iii) 170.315(g)(7)	other applications through a public API (application programming interface), so patients can share health info with tools, applications and platforms they choose • Includes this capability in two places, as access for patients and their authorized representatives in the V/D/T criterion, and as access for developers • ONC believes the criterion can help to address the issue of multiple portals by allows by allowing patients to converge their data from multiple sources into an application of their choice • Requires demonstration of an API that responds to data for any one or more and all of the data in the Common Clinical Data Set o Must establish trusted connection (security), identify patient (selection), and respond to different types of data requests. o Additional data are permitted and encouraged	clinician-facing access; the NPRM rightfully calls this out as its own certification criterion. • (REVISED) Amend: Requirement and testing of APIs need to go beyond APIs' ability to respond to requests for patient data from other applications; needs to ensure that all functionalities present in VDT are enabled (e.g. view, download, transmit, patient-generated health data, secure messaging) • Amend: Access to the Common Clinical Data Set alone is not enough, and access must include items like care plans, referral summaries, discharge instructions and patient health information (e.g. advance directives). • Comment: To ensure a truly public and open API, documentation must be publicly available and free to developers, and no non-disclosure agreement should be required to view it—no barriers to access or use. Documentation should also include examples of requests and responses.
Secure Messaging 170.315(e)(2)	UNCHANGED from 2014 edition • Enable a provider to send encrypted messages electronically to patients and receive electronic messages from patients	• Repeating prior comments on the 2015 voluntary edition: o Comment: EHR technology should be capable of tracking the response to a patient-generated message (e.g., no response, secure message reply, telephone reply). o Comment: Tracking the timeframe for response. We do not propose requiring a specific timeliness standard. o Comment: Secure messaging should have the ability to provide messages in languages other than English.
Clinical Decision Support (CDS) 170.315(a)(10)	• Capability to record at least *one* CDS intervention taken and by whom--*e.g.,* whether the provider viewed, accepted, declined, ignored, overrode, provided a rationale or explanation for the action taken, took some other type of action not listed here, or otherwise commented on the CDS intervention	• Support: Because CDS is a primary means of applying best evidence and new knowledge at point of care, recording the action taken without impeding workflow makes sense. • Amend: require that EHR technology demonstrate the capability to use at least two of the demographic data elements to activate CDS; ONC proposed this capability to use at least one demographic data element in 2015 voluntary edition NPRM. • Amend: include family health history in the data categories for the CDS criterion • Amend: Include patients and families as equal decision makers, current recommended standards do not support this and should not be considered. *ONC seeks comment on:*

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		• Should Clinical Decision Support (CDS) criterion also require requesting patient-specific education resources based on preferred language? ○ Support: CDS is a primary means of applying best evidence and knowledge at the point and time of care. That is the prime moment to request patient-specific education materials in the patient's preferred language.
Data Portability 170.315(b)(6)	• Gives providers easy access and ability to export clinical data about patients for use in different EHRs or third party systems • Export summary for given patient and all patients includes Common Clinical Data Set, encounter diagnoses, cognitive status, functional status, reason for referral (ambulatory), discharge instructions (inpatient) • Can create summary based on relative date/time; specific date/time; when user signs note/order	
Amendments 170.315(d)(4)	*UNCHANGED from 2014 edition.* • Enables providers to accepts or deny request amendments, and appends it to patient's record	• Amend: CEHRT must be able to maintain the provenance of amendments and other PGHD.
Authentication, Access Control, and Authorization 170.315(d)(1)	*UNCHANGED from 2014 edition.* • Verifies identity and allowed types of access and actions person may take	