



POLICY & ACTION FROM CONSUMER REPORTS

April 28, 2014

Submitted electronically

Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
ATTN: 2015 Edition EHR Standards and Certification Criteria Proposed Rule
Hubert H. Humphrey Building
Suite 729D, 200 Independence Ave, S.W.
Washington, D.C. 20201

RE: Notice of Proposed Rulemaking—RIN 0991-AB92—Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements

Dear Dr. DeSalvo:

Consumers Union, the policy and advocacy division of Consumer Reports, appreciates the opportunity to provide input on the 2015 Edition Electronic Health Record (EHR) Certification Criteria. Health Information Technology (Health IT) can improve health outcomes, empower patients to participate actively in their care, generate research data to improve population health, and improve the effectiveness of the American health system. Health IT can deliver needed benefits to individual and population health: better healthcare outcomes for individuals, better decision-making and care coordination by providers, and greater engagement of patients and families in their care. Patients and consumers need better public health outcomes; the improved quality, safety, and efficiency of healthcare as well as the reduction of unnecessary care and costs. Health IT capabilities are rapidly evolving and we are pleased to see the ONC taking advantage of these advancements.

Our comments on specific proposals are included below. Although we do not comment on some proposals included in the proposed rule, our silence does not indicate disapproval, and we have signed-on to the Consumer Partnership for eHealth (CPeH) comment letter, where more extensive comments are provided.

§170.315(a)(5) Demographics

We thank ONC for including recommendations to build upon and improve the demographics criterion. Consumers Union supports health IT standards that facilitate active engagement of patients in their healthcare. We therefore wholeheartedly support ONC's goal of including all languages currently in use for the patient/patient caregiver's preferred language(s), as the current standard for recording patient language preferences is inadequate. We believe that more granular identification of a patient's preferred language is tightly linked to meaningful transmission of information about consumers' health and care, leading to better understanding and better outcomes.

Headquarters Office
101 Truman Avenue
Yonkers, New York 10703-1057
(914) 378-2029
(914) 378-2992 (fax)

Washington Office
1101 17th Street, NW #500
Washington, DC 20036
(202) 462-6262
(202) 265-9548 (fax)

West Coast Office
1535 Mission Street
San Francisco, CA 94103-2512
(415) 461-6747
(415) 431-0906 (fax)

South West Office
506 West 14th Street, Suite A
Austin, TX 78701
(512) 477-4431
(512) 477-8934 (fax)

We oppose using ISO-639-2 codes for the reason detailed in the NPRM: particular spoken languages are not in all cases sufficiently supported. The ISO-639-2 coding protocol is intended for written languages and does not include spoken languages, such as Cantonese or other Chinese dialects, or sign language. We decline to recommend either alternative proposed by the NPRM over the other—ISO-639-3 versus RFC 5646—so long as the standard adopted achieves the goal of inclusiveness and adoption of EHR technology that supports each consumer’s preferred language.

§ 170.315(a)(14) Image Results

Although there is no change proposed for the 2015 Edition EHR imaging result certification criterion, we encourage ONC to require that images be of diagnostic quality. We have no preference whether EHR technology links to images or stores images within the EHR, but in any case, the images must be of diagnostic quality in order to be valuable to consumers seeking to transmit the images to additional providers.

§ 170.315(a)(15) Family Health History

We support actions taken towards improving health history standards and enhancing interoperability between EHR technology while refraining from comment on specific standards used. Family health history is a valuable tool in providing tailored healthcare; steps towards increasing precision of health history data and communication between providers—and interoperability between their health records—is likely to improve patient care.

§ 170.315(a)(16) Patient List Creation

We support the proposal to require that EHR technology demonstrate its capability to use at least one of the more specific data categories included in the “demographics certification criterion.” Stage 3 is ONC’s opportunity to improve data collection by improving providers’ ability to stratify patient data by disparity variables. This technology would enable providers to improve quality of care by identifying and rectifying shortcomings in care for impacted populations. ONC’s proposal represents much-needed progress from the first two stages of Meaningful Use, which required providers to record a consumer’s demographic information and to generate at least one list of patients by specific condition. However, there was no parallel requirement to generate lists of patients by disparity variables such as race, ethnicity, language, gender identify, sexual orientation, socio-economic status, or disability status.

The ability to create patient lists is particularly important for generating patient reminders for preventive and follow-up care, which are valuable tools for patient engagement. However, they are only useful when provided in a format that the consumer understands (in their preferred language) and is able to receive (in their preferred format). For these reasons, consumers stand to benefit from EHR technology that is capable of drawing from consumers’ demographic information to package and deliver information. The ONC’s proposal that EHR technology be able to generate lists based on only one demographic variable seems a very minimal standard. Consumers Union therefore urges ONC to make standards more robust by requiring that EHRs have the capability to use more than one specific data category for list making. This would allow providers to generate lists that more accurately reflect the full range of patient identities so that they can better tailor care to reflect their patient’s needs.

Our responses to ONC's questions regarding the 2017 Edition are as follows.

(1) *Whether patient communication preferences should be a requirement for the inpatient setting.*

Yes, patient communication preferences should be required for the inpatient setting. We further urge ONC to recognize that patient communication preference is always important, regardless of whether care is delivered in the inpatient or outpatient setting. We believe that a minimum list of patient communication preferences should be the absolute floor for what is expected from EHRs, and being able to filter based on the patient's preferred language should be a given. Consumers Union suggests that this component be included in the proposal for 2015, rather than waiting until 2017, wherever possible.

(4) *Whether [ONC] should include within this certification criterion or adopt a new certification criterion that would require EHR technology be able to provide patient reminders according to identified patient preferences and preferred language.*

As detailed in our response to proposal §170.315(1)(16), *infra*, patient reminders are essential tools for patient engagement. However, it is critically important that these reminders be generated and delivered in the patient/caregiver's preferred language *and* preferred mode of communication. Research indicates that some underserved populations with the most health risks have significant difficulty communicating with their providers, mostly due to language issues (irrespective of the availability of interpreter services), leading to worse health outcomes.^{1, 2} A patient reminder provided in a language the patient/caregiver does not adequately understand, or in a format that is inaccessible, fails to serve the very purpose for which it was designed. Although we do not have a position on whether to require this capability in the existing or a separate criterion, we do urge ONC to make this functionality available at the earliest possible date.

§ 170.315(a)(19) *Advance Directives*

We strongly urge the ONC to advance the utility of this requirement in the 2015 Edition. Knowing the existence *and location* of a consumer's advance directive increases the likelihood that his preference will be honored at what may be the most important and personal moment in care: end of life. Unfortunately, the 2014 standard falls short by failing to record the *content* and *location* of an advance directive, and by limiting recording of information on an advance directive to a subset of the population (hospitalized patients aged 65 and older). We therefore recommend that the ONC expand the certification criteria in each of these areas.

Our recommendation here echoes input from federal legislators who, in September 2013, called for progress in this criterion. In a bipartisan letter³ from eight members of the U.S. House of Representatives, lawmakers called on ONC to advance care planning, including the advance directive objective, in the third stage of Meaningful Use.

¹ Collins KS, Hughes DL, Doty MM, Ives BL, Edwards JN, Tenney K. Diverse Communities, Common Concerns: Assessing Health Care Quality for Minority Americans. The Commonwealth Fund, March 2002. Available at <http://www.commonwealthfund.org/Publications/Fund-Reports/2002/Mar/Diverse-Communities--Common-Concerns--Assessing-Health-Care-Quality-for-Minority-Americans.aspx> (accessed April 10, 2014).

² Hablamos Juntos and Robert Wood Johnson Foundation. Physician Perspectives on Communication Barriers: Insights from Focus Groups with Physicians Who Treat Non-English Proficient and Limited English Proficient Patients. March 2004. http://www.hablamosjuntos.org/pdf_files/lsp.report.final.pdf (accessed April 10, 2014).

³ Letter to the Office of the National Coordinator for Health Information Technology, dated September 18, 2013, and signed by Earl Blumenauer, Tom Petri, Allyson Schwartz, Richard Hanna, Jim McDermott, Jan Schakowsky, Lois Capps, and Scott Peters. http://www.healthit.gov/sites/default/files/archive/FACA%20Hearings/2013-09-23%20Policy%3A%20Certification%20%26%20Adoption%20WG,%20Care%20Planning%20Virtual%20Hearing/2013_09_18_AdvanceDirectivesLetter.pdf (accessed April 9, 2014).

§ 170.315(a)(20) Implantable Device List

We support ONC's proposal to adopt a new 2015 Edition certification criterion requiring EHR technology to enable a user to electronically record the unique device identifier (UDI) of an implantable device as well as other contextually relevant information associated with a patient's implantable devices (such as a procedure note, e.g. recording whether the doctor modified the device before implant, or additional information about the device). With nearly 1.2 million hip and knee surgeries performed in the U.S. each year⁴—and with this number growing rapidly—the need to track the implantation and outcomes of each device becomes increasingly important both for patient safety and product improvement. We therefore support proposals, such as this one, which strengthen consumers' access to information about what devices are in their bodies, making it easier to share that information with healthcare providers, and enabling consumers to be vigilant to alerts and recalls for the multi-decade life of their device. We further envision the coupling of a feature like this with the development of a national implantable device registry.⁵ Finally, we agree that EHRs should facilitate UDI exchange in the transitions of care, data portability, view/download/transmit, and clinical summary criterion.

§ 170.315(c)(4) Clinical Quality Measures – Functions and Standards for CQM Certification

In response to this NPRM's request for recommendation on specific capabilities, reporting requirements, standards, and data elements ONC should consider for CQM certification, we strongly urge ONC to require that EHRs have the capacity to record consumer satisfaction measures. Some of the best data on clinical quality comes from consumers. Tools already exist and are available for use that captures outcomes from the consumer perspective. For example, the Consumer Assessment of Healthcare Providers and Systems (CAHPS) is a standardized and tested survey tool developed by the Agency for Healthcare Research and Quality (AHRQ) to access consumers' experiences with healthcare.⁶ ONC should therefore motivate EHR technology developers to create the capacity for their technology to collect and make use of this information by the 2017 Edition, if not before.

We also recommend that ONC include *safety* measures in their CQM standards. For example, that EHRs capture elements required to identify hospital acquired conditions (HACs) that hospitals report to CDC's National Healthcare Safety Network for state or federal public reporting programs. A recent study estimates that 440,000 people die each year after suffering a medical error in the hospital.⁷ Many more are harmed by errors and unsafe practices as outpatients. Individual and population health stands to benefit by the inclusion of safety measures. For example, recording these experiences in the EHR will enable providers, researchers, consumers, and advocates to identify and avoid practices linked to errors.

⁴ Press Release: Consumers Union Takes Push for Hip and Knee Implant Warranties To Orthopaedic Surgeons Conference in New Orleans, March 11, 2014. http://safepatientproject.org/press_release/5045 (accessed April 9, 2014).

⁵ A Consumer Reports poll found that 95% of Americans believe that effective consumer protections for medical implants should include a nationwide system for tracking medical implants so patients can be notified about safety problems or recalls. Press Release: Consumer Reports Poll: Americans Overwhelmingly Support Strong Medical Device Safety Oversight. http://safepatientproject.org/press_release/consumer-reports-poll-americans-overwhelmingly-support-strong-medical-device-safety-oversight (Accessed April 9, 2014).

⁶ For more information, see Mathematical Policy, Inc., *Literature Review: Using Quality Information for Health Care Decisions and Quality Improvement*, May 6, 2005. Available at <https://cahps.ahrq.gov/about-cahps/qualityinfo.pdf> (accessed April 10, 2014) and AHRQ's website on CAHPS: <https://cahps.ahrq.gov/about-cahps/index.html> (accessed April 10, 2014).

⁷ Consumers Union, *Survive Your Hospital Stay*, March 2014. Available at <http://www.consumerreports.org/cro/magazine/2014/05/survive-your-hospital-stay/index.htm> (accessed April 10, 2014).

§ 170.315(c)(4) Clinical Quality Measures – Patient Population Filtering

We support ONC’s proposal to require that EHR technology be able to filter clinical quality measure (CQM) results to create different patient population groupings by one or a combination of listed consumer characteristics. We further recommend that stratifications be based on more than one variable, and also encourage ONC to expand the list of demographic details to include race, ethnicity, sexual orientation, gender identity, and disability status as early as each can reasonably be expected to be adopted into EHR technology.

Collecting and using information about provider quality is one of the cornerstones of increasing quality and cost transparency so consumers can make educated healthcare purchasing decisions. EHRs are a valuable tool for collecting information and manipulating that data to create a picture of health outcomes and draw conclusions about provider quality. At the same time, surveys indicate the majority of American healthcare consumers support research uses of data but are concerned about the privacy of their medical information.⁸ We therefore urge caution any time sensitive consumer information is involved—as is the case with healthcare. In this proposal, it is unclear what this EHR capability will be used for, and by whom. Therefore, although we value the use of EHRs to improve individual and population health, we strongly encourage ONC to develop guidance so consumer privacy and online security are protected.

§ 170.315(D)(4) Amendments

Amendments are an important form of consumer generated health data. Increased access by individuals to their own health information, as a result of initiatives such as Blue Button and the meaningful use of View, Download, and Transmit (VDT) criteria are likely to increase the number of errors identified by consumers, thereby highlighting the need for an amendments function to the EHR. We therefore urge ONC to add to the certification standard that EHR technology must be capable of maintaining the provenance of this and other consumer-generated health information. To that end, ONC should confirm whether the 2015 Edition must add any specifications to the 2014 Edition to include this functionality.

§170.315(e)(1) View, Download, and Transmit to Third Party

The ability to view, download, and freely transmit (VDT) one’s own health information is a focal point for consumer advocates; correctly implemented, it promises to increase consumer engagement and improve health outcomes. We enthusiastically welcome the proposals here, both for 2015 and for 2017, as they will improve the usability of VDT technology for consumers and their caregivers. In addition, as explained in §170.315(D)(4), *infra*, once consumers are able to view and download their health information, errors are likely to be uncovered; consumers must therefore also have the ability to amend their records as part of the VDT process.

2015 Edition Issues for the VDT Certification Criterion Under Consideration

We support ONC’s clarification that VDT functionality should be patient-facing, and appreciate and support the specific reference to authorized representatives in the criterion. In many cases, family members and other caregivers are essential members of a consumer’s health team and therefore should have access to VDT technology as an extension of the consumer. Allowing patients to specify

⁸ Okun, S., D. McGraw, P. Stang, E. Larson, D. Goldmann, J. Kupersmith, R. Filart, R. M. Robertson, C. Grossmann, and M. D. Murray. 2013. Making the case for continuous learning from routinely collected data. Discussion Paper, Institute of Medicine, Washington, DC. <http://www.iom.edu/makingthecase> (accessed April 11, 2014).

with whom they want to share health information is a critical aspect of consumers' vision for the next generation of health and care planning, as well as for information sharing in general. As a logical extension of ONC's attempt to make EHR technology "patient facing," we support the proposal that patients must be able to download ambulatory or inpatient summary in a "human readable" format as well as the Consolidated CDA version.

We support the proposal to add "implantable device information" as data consumers would be able to access under the "view" capability of their provider's EHR for the reasons detailed in our comments on §170.315(a)(20), *infra*. This will also facilitate electronic exchange of UDI via VDT.

As explained in our feedback on the proposal for §170.315(c)(4), *infra*, we value Health IT for its contribution towards improved individual and population health while stressing the importance of healthcare data privacy and security. We therefore support the proposed two new data points in the 2015 Edition VDT criterion related to the activity history log. Recording the addressee to whom an ambulatory summary or inpatient summary was transmitted, and whether that transmission was successful or failed, provides both a deterrent for inappropriate access to consumer data and a way to track—and prosecute—malfeasance.

Finally, for the 2015 Edition, we are pleased by ONC's efforts to improve access and viewing of health information for individuals with disabilities by requiring that EHR technology be compliant with Level AA. To confirm the value of this advancement, we recommend ONC have individuals with disabilities test the system to ensure accessibility and usability. We also encourage ONC to ensure that EHR systems are usable by providers with disabilities in addition to consumers.

2017 Edition Issues for the VDT Certification Criterion Under Consideration

We support ONC's proposal to require EHR technology be capable of transmitting medical images of diagnostic quality. We agree with the ONC that doing so would empower consumers to play a greater role in their own care coordination and could assist in reducing the amount of redundant and duplicative imaging-oriented tests performed, simultaneously reducing costs and improving consumer experience in the healthcare system. In response to ONC's query in the NPRM, diagnostic images must be not only viewable and downloadable but also transmittable; not requiring the third element devalues the first two.

Finally, we support enabling "OpenNotes" functionality for EPs, EEs, and CAHs in the 2017 Edition VDT certification criterion. In adopting this function, ONC would provide consumers truly comprehensive and transparent access to their health information. The results of the OpenNotes initiative⁹ were striking only in part because of its seemingly straightforward conclusion: that healthcare improved for consumers and the burden on providers was arguably nil. Indeed, patients reported positive healthcare experiences and nearly universally wanted OpenNotes to continue, while doctors reported minimal impact on their practice and none elected to stop when the study concluded.¹⁰ Given these results, the time has clearly come to release to consumers *all* healthcare information that relates to their care.

⁹ Tom Delbanco, MD*; Jan Walker, RN, MBA*; Sigall K. Bell, MD; Jonathan D. Darer, MD, MPH; Joann G. Elmore, MD, MPH; Nadine Farag, MS; Henry J. Feldman, MD; Roanne Mejilla, MPH; Long Ngo, PhD; James D. Ralston, MD, MPH; Stephen E. Ross, MD; Neha Trivedi, BS; Elisabeth Vodicka, BA; and Suzanne G. Leveille, PhD, RN, [Inviting Patients to Read Their Doctors' Notes: A Quasi-experimental Study and a Look Ahead](http://annals.org/article.aspx?articleid=1363511), *Annals of Internal Medicine*. 2012 Oct;157(7):461-470. Available at <http://annals.org/article.aspx?articleid=1363511> (accessed April 9, 2014). *Id.* at 461.

¹⁰ Of 5391 patients who opened at least 1 note and completed a post-intervention survey, 77% to 87% across the 3 sites reported that open notes helped them feel more in control of their care; 60% to 78% of those taking medications reported increased medication adherence; 26% to 36% had privacy concerns; 1% to 8% reported that the notes caused confusion, worry, or offense;

§170.315(e)(3) Secure messaging

We encourage ONC to leverage the 2015 Edition to accelerate changes in the secure messaging criterion currently under consideration for Stage 3 of the meaningful use program. Interaction between consumers and their providers via secure messaging benefits both sides of the line of communication. Indeed, the association between secure messaging and decreased office visits and telephone communication is documented¹¹ as saving time for patients and providers and saving healthcare dollars. In addition, consumers have reported satisfaction with this tool, reporting that it allows “health issues to be closely monitored without the inconveniences of traffic, parking, insurance copayments, or lost days at work. It provides patients with written advice that might be forgotten or misunderstood if communicated verbally and avoids the annoyance of ‘telephone tag.’”¹²

For all its benefits, secure messaging is only meaningful if providers respond in a timely manner. We therefore encourage ONC to measure the timeliness of provider responses. Although we refrain from recommending a specific timeliness standard, we do encourage the measurement and reporting of timeliness rates, as is current practice for industry leaders such as Kaiser Permanente.

Looking towards the 2017 Edition, we encourage ONC to add to the secure messaging criterion the ability to provide messages in languages other than English. This functionality could be the key to improved communication with providers, and lead to improved health outcomes and reduced errors.

Non-Meaningful Use EHR Technology Certification

As a general comment, more robust standards are necessary to foster information sharing across more participants in the system. Consumers of healthcare exist in a variety of settings outside the listed Meaningful Use eligible providers: in nursing facilities, behavioral care settings, and home-based care. Engaging providers in health IT adoption programs would improve healthcare on the individual and population level and improve consumer engagement and likely health outcomes on the individual level.

Other Topics for Consideration for the 2017 Edition certification Criteria Rulemaking: (A) Sexual Orientation and Gender Identity

We support ONC’s suggestion to collect sexual orientation and gender identity (SO-GI) data in order to maximize the value of health IT for patients and providers. A leading assessment of the acceptability and feasibility of asking patients SO-GI questions urges that SO-GI “data collection is a key component of enhancing the ability of patients and providers to engage in meaningful dialogue in the exam room and to promote the provision of high-quality care for LGBT people.”¹³ We believe

and 20% to 42% reported sharing notes with others. ... After the intervention, few doctors reported longer visits (0% to 5%) or more time addressing patients' questions outside of visits (0% to 8%), with practice size having little effect; 3% to 36% of doctors reported changing documentation content; and 0% to 21% reported taking more time writing notes. ... At the end of the experimental period, 99% of patients wanted open notes to continue and no doctor elected to stop.

¹¹ Zhou YY, Garrido T, Chin HL, et al. Patient access to an electronic health record with secure messaging: impact on primary care utilization. *Am J Manag Care*. 2007;13:418–424. Available at <http://www.ajmc.com/publications/issue/2007/2007-07-vol13-n7/Jul07-2509p418-424/> (accessed April 9, 2014). Chen C, Garrido T, Chock D, et al. The Kaiser Permanente electronic health record: transforming and streamlining modalities of care. *Health Aff (Millwood)*. 2009;28:323–333. Available at <http://content.healthaffairs.org/content/28/2/323.long> (accessed April 9, 2014).

¹² Chen C, Garrido T, Chock D, et al. The Kaiser Permanente electronic health record: transforming and streamlining modalities of care. *Health Aff (Millwood)*. 2009;28:323–333. Available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3140444/> (accessed April 9, 2014).

¹³ The Fenway Institute and Center for American Progress, Asking patients questions about sexual orientation and gender identity in clinical settings: A study in four health centers, p.5. 2013. Available at http://thefenwayinstitute.org/wp-content/uploads/COM228_SOGI_CHARN_WhitePaper.pdf (accessed April 23, 2014). Citing Makadon H. Ending LGBT invisibility in health care: The first step in ensuring equitable care. *Cleve Clin J Med*. 2011; 78: 220-224.

that enabling users to electronically record, change, and access data on a patient's SO-GI is clinically relevant and valuable for improving health outcomes. Although we share ONC's concern that current privacy and data security standards may not be adequately protective of SO-GI information in electronic records, we do not see this as a valid reason to avoid collecting this data altogether. Rather, we strongly encourage ONC to develop consumer privacy and online security measures hand-in-hand with the adoption of SO-GI measures in Health IT.

Although we fully support the expansion and inclusion of SO-GI measures in health IT, we refrain from recommending specific code sets. We are, however, concerned that the code sets suggested by ONC—SNOMED CD for sexual orientation and SNOMED CT for gender identity—fail to achieve the goals of Meaningful Use because of inappropriate use of terminology and concepts that do not accurately capture the full spectrum of patients' lives. Instead, we suggest that ONC look towards organizations like The Fenway Institute and the Center for American Progress for guidance on developing new codes that reflect SO-GI data as captured in questions that have been shown to work effectively in clinical settings.¹⁴

Other Topics for Consideration for the 2017 Edition certification Criteria Rulemaking: (G) Blue Button

We are very supportive of Blue Button +, which enables consumers to access their records in a human-readable and/or machine-readable format—whichever the consumer prefers—and in a format which can be sent to whomever she chooses (from printing to sharing with third party applications). Although we lack the technical expertise to comment on the various Blue Button + technical specifications proposed by ONC, we are supportive of the intent. We do, however, urge that the specifications include a requirement that the technology work with a single click or single pass, not requiring endless certification or credentialing on the consumer's end of the technology.

Once again, we thank ONC for the opportunity to comment on the proposed 2015 Edition of certified EHR technology. We recognize this is an advancement for consumers nationwide and eagerly anticipate the improved care and outcomes at lowered costs that will follow thoughtful design and implementation of these criteria.

Sincerely,



Dena B. Mendelsohn, JD, MPH
Health Policy Analyst
Consumers Union

¹⁴ *Id.*