April 28, 2014

Submitted electronically

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

The undersigned consumer organizations and members of the Consumer Partnership for
eHealth (CPeH) submit the following comments. The CPeH is a coalition of more than 50
consumer, patient, and labor organizations working at the national, state, and local levels to
advance private and secure health information technology (health IT) in ways that
measurably improve the lives of individuals and their families. The combined membership
of CPeH represents more than 127 million Americans.

CPeH appreciates the opportunity to provide input on the 2015 Edition Electronic Health
Record (EHR) Certification Criteria. The Notice of Proposed Rulemaking (NPRM) is an
important step in the effort to ensure that health IT facilitates better care, better outcomes,
and lower costs, and clearly reflects a commitment to meeting the needs of patients and
families. In general, we agree that updating certification criteria more frequently as new
knowledge, policies and standards are developed, allows vendors, doctors, and hospitals to
begin incorporating them sooner for everyone's benefit, including the benefit of patients and
families.

Importantly, the NPRM contains a number of recommendations consistent with CPeH's
Disparities Action Plan[1] and Care Plans 2.0 report.[2] The result of a year-long review of
scientific literature and collaboration with experts on disparities and health IT, the

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[1] Leveraging Meaningful Use to Reduce Health Disparities: An Action Plan. Available at
http://www.nationalpartnership.org/research-library/health-care/HIT/leveraging-meaningful-use-to.pdf.
[2] Care Plans 2.0: Consumer Principles for Health and Care Planning in an Electronic Environment.
Available at http://www.nationalpartnership.org/research-library/health-care/HIT/consumer-principles-for-
1.pdf.

Disparities Action Plan focuses on data collection and use to identify disparities; language, literacy, and communication; and care coordination and planning. We are heartened to see many of the Action Plan's recommendations reflected in the proposed rule and appreciate attention to the role that certified EHRs can play in helping providers identify and reduce health disparities.

Our comments on specific proposals are included below. While we have not commented on several proposals included in the proposed rule, such as the public health-related provisions, we nevertheless want to underscore their importance to consumers. Syndromic surveillance data, for example, are valuable for early detection of outbreaks, monitoring disease and condition trends, and providing reassurance that an outbreak has not occurred.

§ 170.315(a)(4) - Drug-Drug, Drug-Allergy Interaction Checks
Automatic drug-drug and drug-allergy checks for contraindications can identify potential medical errors before they occur and thus are valuable for enhancing patient safety and optimizing health outcomes. Accordingly, we support the proposal to require EHR technology to track, automatically and electronically, the user's responses to drug-drug, drug-allergy notifications, much like an audit log automatically records events. Logging the user's response need not impede the user's workflow, but merely captures important information for doctors, patients, and administrators. In our view, any adjustment for perceptions about the severity of an adverse reaction defeats the very purposes of the interaction check and the log of the user's response. Going forward, we encourage the Office of the National Coordinator for Health Information Technology (ONC) to consider how to leverage patient-generated health data to inform drug interaction and intolerance-related notifications (including over-the-counter medications).

§ 170.315(a)(5) - Demographics
We thank ONC for including recommendations to build upon and improve the demographics criterion. In order to reduce health disparities, we need a better understanding of their prevalence and root causes. This can only be accomplished through the collection and capture of more granular, standardized data. Access in EHRs to demographic factors pertinent to individuals' health will help clinicians to address health care disparities more effectively.

There is widespread agreement that the identification and elimination of health disparities should be a national priority. Not only did our Disparities Action Plan highlight the importance of granular demographic data collection, but legislators from both the U.S. Senate and the U.S. House of Representatives also emphasized the need for improved data collection standards in letters sent to ONC and the Centers for Medicare & Medicaid Services (CMS). Additionally, in response to an action alert sent by the National

Partnership for Women & Families, over 4,300 Americans from all 50 states, Washington, DC, Puerto Rico, and the U.S. Virgin Islands sent letters urging ONC to leverage Meaningful Use to reduce health disparities, including by improving demographic data collection.

We strongly support ONC's goal to include in the EHR all languages preferred by the patient. Identification of a patient's preferred language will enable providers to better support patients by providing them meaningful and useful information about their health and care in languages they understand and are comfortable using, thereby improving patient safety and care quality. Certified EHR technology should support providers' ability to address individuals' language needs and preferences, whatever they are (deaf individuals who use American Sign Language or Mandarin, for example). We rely on ONC to identify the appropriate coding system to achieve this goal.

Once fully captured, health care providers can be better prepared to engage and treat patients with language preferences other than English. We appreciate and support that ONC is considering as well how certified EHR technology could incorporate and benefit from this information before an initial visit occurs, for example helping providers to arrange the resources necessary to accommodate the patient's preferred language. We trust that ONC will require certified EHR technology to have the capability to prompt providers to schedule in-person language interpreters for upcoming patient appointments.[3] This is consistent with Health and Human Services (HHS) policies to reduce health disparities and will facilitate providers' compliance with civil rights laws and regulations.[4]

We also encourage ONC to transition from the current (OMB) standards for race and ethnicity data collection to the HHS standards in the 2015 Edition. The HHS standards build upon the Office of Management and Budget (OMB) standards but add more granularity for Asian and Latino populations (as is currently offered by the American Community Survey (ACS) and Decennial Census). Proper identification of important characteristics of sub-populations is necessary because different ethnic groups often have vastly different health profiles. For example, Indian-American adults are nearly three times more likely to have diabetes than Japanese-American adults, but are less likely to have hypertension.[5] Moreover, a requirement for certified EHRs to use the HHS data

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[3] For example, in Washington state, where Medicaid providers use a web-based scheduling portal, the certified EHR technology could be utilized to link providers to the scheduling portal. See http://hca.ctslanguagelink.com/scheduling.php.

[4] Title VI of the Civil Rights Act of 1964, 42 U.S.C. § 2000d; Exec. Order No. 13,166, 68 Fed. Reg. 50121 (August 16, 2000); Section 504 of the Rehabilitation Act, 29 U.S.C. § 794; Section 1557 of the Patient Protection and Affordable Care Act, 42 U.S.C. § 18116.

[5] Barnes PM, Adams PF, Powell-Griner E. Health Characteristics of the Asian Adult Population: United States, 2004-2006. Adv Data. 2008 Jan 22; (394): 1-22.

collection standards is consistent with the requirements of section 4302 of the Patient Protection and Affordable Care Act for data collection standards for race, ethnicity, sex, language, and disability status.[6] We believe such alignment is desirable and consistent with the agency's interest in avoiding duplicative and unnecessarily burdensome requirements.

We are pleased that ONC has proposed to collect socioeconomic status as part of demographic data collection. We encourage ONC to draw on the recently released recommendations from the Institute of Medicine (IOM) consensus study on Recommended Social and Behavioral Domains and Measures for Electronic Health Records, which identify domains and measures that capture the social determinants of health, to inform the development of recommendations for Stage 3 of Meaningful Use.[7] Information about patients' social and behavioral determinants of health complements clinical information and is critical to achieving the Triple Aim of better care, better health, and lower costs.

According to Robert Wood Johnson Foundation's assessment, medical care delivery determines only an estimated 10-15 percent of health. The remaining 85-90 percent of health is determined by other factors, such as health behaviors, genetics, and the socioeconomic and physical environment (e.g., access to education and job opportunities, housing, public safety, language services, availability of places to exercise, healthy food choices, and other environmental factors).[8] Health providers need a standardized method for collecting non-clinical patient health indicators, particularly providers serving vulnerable populations with more complex needs, such as community health centers. Therefore, information about these factors should be collected, recorded, and integrated in a structured format. Identifying a standardized way to record this information also has important implications for patient-generated health data because in many instances patients will be the best source of information about social determinants of their health. To supplement the IOM's recommendations, we encourage ONC to solicit advice from knowledgeable consumers and providers, such as a community advisory board, to ensure a comprehensive list of non-clinical patient health indicators.

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[6] U.S. Dept. of Health and Human Services, Office of Minority Health. Explanation of Data Standards for Race, Ethnicity, Sex, Primary Language, and Disability.
http://minorityhealth.hhs.gov/templates/content.aspx?ID=9228.

[7] Capturing Social and Behavioral Domains in Electronic Health Records: Phase 1. Institute of Medicine. Released April 8, 2014. Available http://iom.edu/Reports/2014/Capturing-Social-and-Behavioral-Domains-in-Electronic-Health-Records-Phase-1.aspx?utm_medium=etmail&utm_source=Institute%20of%20Medicine&utm_campaign=04.08.14+New+Report+-+EHR+1&utm_content=&utm_term=.

[8] Robert Wood Johnson Foundation, Frequently asked questions about the social determinants of health (2010), available at
http://www.rwjf.org/content/dam/files/rwjfwebfiles/Research/2010/faqsocialdeterminants20101029.pdf.

§ 170.315(a)(10) - Clinical Decision Support
We were heartened to see the proposal to require EHR technology to demonstrate the capability to activate clinical decision support (CDS) interventions using at least one of the "demographics" data categories (e.g., sex or date of birth). This is a critical functionality we highlighted in the Disparities Action Plan, noting that demographics-based CDS tools and shared decision making tools can help fill knowledge gaps in clinical guidelines for care, and help to improve care for underserved populations such as transgendered individuals. However, this proposal makes it all the more necessary to obtain more granular data that would be achieved by transitioning from OMB to HHS standards.

In addition, we encourage ONC to include family health history in the data categories for the CDS criterion. For example, a woman's family history of breast cancer might prompt a recommendation for mammogram screenings at an earlier age than currently recommended by the U.S. Preventive Services Task Force. Adding family health history to CDS rules could provide pertinent clinical information, and could also strengthen and improve the standards for family health history.

Finally, the proposed requirement to use "at least one" demographic data element is not sufficient. As the nation becomes more diverse, a single demographic data element cannot adequately meet the needs of all populations. Therefore, we encourage ONC to require that EHR technology demonstrate the capability to use <u>at least two</u> of the specific data categories, wherever relevant, to facilitate providers' ability to better tailor care to their patients' needs.

§ 170.315(a)(11) - Electronic Notes
We support the proposal to require EHR technology to have the capability to search for information across separate notes within the EHR systems, rather than just within one particular note. This functionality is critical to identifying patterns among a patient population, which may in turn be helpful in distinguishing previously unidentified disparities in care delivery or health outcomes. This functionality would help to maximize the utility of the information stored in electronic notes, as well as reduce the time providers spend looking for specific patient information.

If the capability allows providers to search across the notes of different patients within the EHR, then the function should be structured in such a way that it observes the special privacy protections for certain sensitive categories of personal health information, such as substance abuse, psychotherapy notes, and HIV test results.

§ 170.315(a)(13) - Smoking Status
We encourage ONC to consider how to capture information about additional forms of tobacco use, such as smokeless tobacco, that may not be adequately captured by the current terminology focused exclusively on smoking status. This is particularly important from a health disparities angle, as certain populations are more likely than others to use smokeless tobacco. For example, among those who use smokeless tobacco, the National Survey on Drug Use and Health indicates that males have higher rates than females, American Indians or Alaska Natives have the highest rates among racial and ethnic groups, rural populations have higher usage rates than those in more metropolitan settings, and populations in the South and Midwest have higher rates of usage than those in the Northeast or West.[9] Moreover, among males between the ages of 12 and 17, use of smokeless tobacco increased significantly between 2002 and 2007,[10] with rates barely dropping since.[11] Providers cannot provide the necessary information and support regarding tobacco use if they are not aware that their patients are using smokeless tobacco.

§ 170.315(a)(14) - Image Results
While there is no change proposed for the 2015 Edition EHR imaging result certification criterion, we encourage ONC to require that, where possible and relevant, diagnostic quality images be made available.

§ 170.315(a)(15) - Family Health History
As noted above, we support ONC's proposal to revise the 2015 Edition family health history certification criterion. It is critical to continue to improve family health history standards and ensure that information can be exchanged and used by providers using different EHR technology.

§ 170.315(a)(16) -Patient List Creation
We support the proposal to require EHR technology to demonstrate its capability to use at least one of the more specific data categories included in the "demographics" certification criterion. Improved data collection and use were recently identified by members from both the U.S. Senate and the U.S. House of Representatives as priorities for Stage 3 of the Meaningful Use Incentive Program, including enhancing providers' ability to stratify patient data by disparity variables. ONC's proposal represents much-needed progress

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[9] Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (February 19, 2009). The NSDUH Report: Smokeless Tobacco Use, Initiation, and Relationship to Cigarette Smoking: 2002 to 2007. Rockville, MD.
[10] Ibid.
[11] Johnston LD, O'Malley PM, Miech RA, Bachman JG, and Schulenberg JE (2014). Monitoring the future national results on adolescent drug use: Overview of key findings, 2013. Ann Arbor, Mich: Institute ofr Social Research, the University of Michigan.

from the first two stages of Meaningful Use, which required providers to record a patient's demographic information and to generate at least one list of patients by <u>specific condition</u>. However, there was no parallel requirement to generate lists of patients by <u>disparity variables</u> such as race, ethnicity, language, gender identity, sexual orientation, socio-economic status, or disability status.

The ability to filter or stratify patient lists by demographic data is critical. It gives providers the capability to more easily identify patterns in their patient populations, and could alert them to specific disparities in care that may have otherwise gone unnoticed and unaddressed. For example, after transforming its practice to collect more granular patient demographics and stratify those data, the Institute for Family Health, a FQHC network in New York City, was able to identify a previously unmet need for hepatitis B screenings among its foreign-born patients from particular areas.[12]

Furthermore, the ability to create patient lists is particularly important for generating reminders. Scientific literature has found that patient reminders help with issues such as medication adherence and management of chronic conditions. One study demonstrated that mobile reminders about checking blood sugar and refilling medications helped patients significantly improve glycemic control and resulted in the health system seeing a net cost savings of nearly nine percent.[13] Additionally, a systematic review of e-reminders found that they led to significant improvement in patients' medication adherence.[14] Enabling providers to create patient lists in order to generate reminders can have significant implications for patients' health outcomes.

Again, we encourage ONC to require that EHR technology be capable of using <u>at least two</u> of the specific demographic data categories to generate lists of patients. 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 patients' needs. While we recognize that this NPRM concerns the criteria for certified EHR technology rather than for the meaningful use of that technology, we underscore that the mere ability to create the list is necessary, but not sufficient. EHR technology must be able to generate patient lists, and providers must then use them.

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[12] Health Research & Educational Trust. (2013, August). Reducing health care disparities: Collection and use of race, ethnicity and language data. Chicago: Health Research & Educational Trust. Retrieved from www.hpoe.org.

[13] Nundy S, Dick J, Chou C, Nocon R, Chin M, and Peek M. Mobile phone diabetes project led to improved glycemic control and net savings for Chicago plan participants. Health Aff. February 2014: vol. 33 no 2. 265-272.

[14] Vervloet M, Linn A, van Weert J, de Bakker D, Bouvy M, and van Dijk L. The effectiveness of interventions using electronic reminders to improve adherence to chronic medication: a systematic review of the literature. J Am Med Inform Assoc. April 2012. doi:10.1136/amiajnl-2011-000748.

We also want to address several questions that ONC posed regarding the 2017 Edition. First, we agree that patient communication preferences should be required for the inpatient setting. This is vital to ensuring that patients receive information in a medium that is most accessible and meaningful to them. However, we encourage ONC to require the use of data on patient communication preferences in conjunction with other requirements, such as discharge instructions (i.e., discharge instructions are required to be provided based on a patient's documented communication preference). To the extent feasible, we recommend that ONC incorporate standards for at least some patient preferences in the 2015 Edition.

We agree that ONC should define a minimum list of communication preferences that every EHR should be able to make available to patients, including, as appropriate, electronically through secure email or a patient portal, paper through regular mail, telephone, and text. Such a list would ensure that a provider can easily identify and meet their patients' communication preferences in all basic, minimum formats, and that all patients can receive critical information in these common formats. We also look forward to the creation of patient reminder lists based on patients' preferred communication methods.

Additionally, certified EHR technology should be capable of using a patient's preferred language as a filter, and eventually provide patient reminders according to identified patient preferences *and* preferred language. 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.[15, 16] Using patients' preferred languages as a filter could help to highlight deficiencies in communication practices and patient education materials. We do not have a position on whether to require this capability in the existing or a separate criterion, but do urge ONC to make the functionality available.

§ 170.315(a)(17) - Patient-Specific Education Resources
We fully support leveraging EHR technology to identify and provide access to meaningful and useful patient-specific education resources. We encourage ONC to make it easy for providers to identify resources tailored to their patients' health status, race, ethnicity, language, functional status, etc. We support an approach that best meets the

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[15] 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.
[16] 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.

goals of making the function useful, saving providers' time and optimizing the quality and utility of education resources for patients.

EHR technology should also be capable of providing patient-specific education resources in a patient's preferred language as soon as possible to ensure that every patient can understand the relevant information. 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. We encourage ONC to look to existing technology as a resource, such as Healthwise and Polyglot Systems Inc.'s Meducation and MeducationDC, which provide medication instructions and patient discharge instructions (respectively) in patients' preferred languages, as well as in formats accessible to patients with visual and auditory impairments.

ONC asks whether it should require that EHR technology be capable of providing patient-specific education resources in a patient's preferred language in the 2015 Edition, in a potential 2017 Edition certification criterion, or in both. In the 2015 Edition, EHR technology should be capable of providing 100 percent of education resources in Spanish. 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 percent, of Americans spoke some language other than English at home. By 2017, therefore, EHRs should be able to provide education materials at least in the top five national languages.

§ 170.315(a)(19) - Advance Directives
We encourage ONC to advance this requirement in the 2015 Edition. Given the capabilities of current technology, it is not sufficient to require EHRs merely to record presence or absence of an advance directive. The specifics of an advance directive constitute essential patient preference information that is necessary for providers to act according to their patients' choices. Patients and providers would benefit significantly from having the *content* of advance directives available at the point of care. Leveraging existing and future technical solutions for making advance directive content available at the point of care is also a meaningful way to incentivize greater information exchange.

In the 2015 Edition, ONC should require EHRs to include a link to or instructions for finding the most recent version of an advance directive, in addition to a notation about its existence. Additionally, certification criteria should require that the capture of this information is possible for any patient (regardless of age), not just those age 65 and older. While the older population benefits most immediately from access to advance directives, unexpected end-of-life incidents can happen at any age. As increasing numbers of hospitals

and practitioners across the country adopt and meaningfully use EHRs, it is critical that their systems can connect providers to this important patient information.

These suggestions echo input from state and federal legislators who have called for strengthening this criterion. In September 2013, a bipartisan letter from eight members of the U.S. House of Representatives called on ONC to advance care planning, including the advance directive objective, in the third stage of Meaningful Use. More recently, a member of the Maryland House of Delegates called on ONC to "raise the bar" on advance directives and require certified EHRs to provide a link to patients' most recent advance directives.

§ 170.315(a)(20) - Implantable Device List
We support ONC's proposal to adopt a new 2015 Edition certification criterion that would require 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 recording whether the doctor modified the device before implant). This capability has important implications for patient safety efforts, such as adverse event reporting, as well as future CDS rules. We also agree that EHRs should facilitate UDI exchange in the transitions of care, data portability, view/download/transmit, and clinical summary criterion. In addition to the criteria outlined in the proposed rule, ONC should also consider how best to provide patients with label information and instructions for a device. This information could occur through the incorporation of UDI via the 'View' functionality of patient portals, for example.

§ 170.315(b)(1)- Transitions of Care
We 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. The updated C-CDA includes new structural elements for care plans, patient goals, and health outcomes that are important to consumers' vision of longitudinal, bi-directional health and care planning.[17] We also generally support a "performance standard" requirement that ensures C-CDAs are able to be successfully exchanged and used, and agree that the proposed 95 percent threshold is an appropriate place to start to ensure high-quality, accurate data that support patient safety and care.

We also support ONC's intention to leverage the TOC criterion to test new approaches to patient matching. Ensuring that individual records from different sources and providers (doctors, hospitals, laboratories, etc.) are properly matched to the correct patient is critical to providing safe, high-quality care.

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[17] Care Plans 2.0: Consumer Principles for Health and Care Planning in an Electronic Environment. Available at http://www.nationalpartnership.org/research-library/health-care/HIT/consumer-principles-for-1.pdf.

We encourage ONC to take into account the diverse characteristics and attitudes among patient populations when designing patient matching processes. For example, an address might work well for many, but does not work well for homeless individuals. No single attribute will work equally well for all patient populations and regions, and the task should be to identify a combination of attributes that collectively works best across the diversity of patient populations. Any development of standards for patient data attributes should acknowledge the wide ethnic and cultural differences of patients, to the extent possible.

Additionally, as patient matching elements are being developed, we encourage that the data field for "sex" be renamed "sex assigned at birth" or "natal sex," while still relying on the HL7 Version 3 Value Set for Administrative Gender. While sex may change throughout the course of a person's lifetime, the sex assigned at birth will not, and is thereby better suited for patient matching efforts.

§ 170.315(b)(2) - Clinical Information Reconciliation and Incorporation
We appreciate ONC's request for feedback on what data beyond medications, medication allergies, and problems should be required to be reconciled. Patients and their caregivers have clinically relevant information to share that should be leveraged in the reconciliation process, particularly for information that is likely to change between health care encounters, including:
- Medications actually taken (including over-the-counter drugs and herbal supplements);
- Caregiver name, contact information, and role;
- Problems/complaints;
- Advance directive status and content;
- Additional care team members (primary care, specialists, ER, retail clinics, etc.);
- Family health history; and
- Vaccinations and immunizations.

We support retaining the external data source's provenance as part of the incorporation process. Retaining data provenance should be standard practice, as it is particularly important for incorporating patient-generated health data. We encourage ONC to incorporate such data provenance in the 2015 Edition to the extent possible.

§ 170.315(b)(6) - Data Portability
We support the intent behind ONC's proposal to rename the criterion "Data Migration" to better describe its focus on data availability from a health care provider's perspective. The ability for providers to accurately export and/or migrate a comprehensive data set of their patient population is paramount for ensuring safe, high-quality care.

The data set available for export should be as complete as possible. That would include expanding the time boundary to allow for more longitudinal data, as the NPRM suggests, as well as clinical notes. Important information is currently captured in the notes sections that should continue to be available if a provider is migrating data to a different EHR system. We encourage ONC to initially focus on including surgical and treatment notes for Eligible Hospitals and visit notes for Eligible Professionals in subsequent data portability requirements. We understand that this should be possible in the 2015 Edition as well as the 2017 Edition.

In general, we agree with ONC's proposal to promote a broader range of use cases for the data portability certification requirement. The types of queries referenced by ONC (local access, targeted access, and multi-source access) will be important to populating and exchanging patient-centered care plans. In 2013, the National Partnership released a report detailing consumer priorities for health and care planning. Consumers envision moving beyond the concept of a care plan as a document fixed in time, to a multidimensional, person-centered health and care planning process built on a dynamic, electronic platform. We encourage ONC to draw upon this report as a resource when considering additional use cases.[18]

§ 170.315(c)(4) - Clinical Quality Measures – Patient Population Filtering
We strongly support ONC's proposal to require that EHR technology be able to filter clinical quality measure (CQM) results to create and stratify different patient population groupings by one or a combination of patient demographic characteristics, including age, sex, preferred language, education level, and socioeconomic status.

This is a critically important functionality discussed in the Disparities Action Plan and called for by Members of Congress in their recent letters to ONC and CMS regarding health disparities. In the Disparities Action Plan, however, we recommend stratifying reported quality measures by at least two disparity variables, with reduction in disparities demonstrated in at least one measure. Doing so ensures that providers will continue to collect and record demographic information as structured data, even as that separate meaningful use requirement is retired.

Moving forward, we urge ONC not to limit the patient characteristics to those listed; ONC should explicitly include race and ethnicity data in the criterion for the 2015 Edition CEHRT, as well as data on sexual orientation, gender identity, and disability status in the 2017 Edition.

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[18] Care Plans 2.0: Consumer Principles for Health and Care Planning in an Electronic Environment. Available at http://www.nationalpartnership.org/research-library/health-care/HIT/consumer-principles-for-1.pdf.

§ 170.315(d)(1) - Authentication, Access Control, and Authorization
We generally support two-factor authentication at level of assurance (LOA) 3 to support use of certified EHR technology for e-prescribing of controlled substances and remote provider access to EHR technology. We have reviewed the recommendations on provider authentication transmitted from the HIT Policy Committee and its Privacy and Security Tiger Team (dated September 26, 2012). We agree with the Tiger Team's reasoning and recommendation to require multi-factor authentication meeting NIST level of assurance 3 for remote provider access to EHRs, e.g., access from outside of an organization/entity's private network, access from an IP address not recognized as part of the organization/entity or that is outside of the organization/entity's compliance environment, and access across a network any part of which is or could be unsecure (such as across the open Internet or using an unsecure wireless connection). The need for provider security and patient trust regarding the patient's health information are highlighted, not diminished, when the provider accesses the EHR remotely, and NIST level of assurance 3 meets that need. The Tiger Team's recommendations noted that the area for exploration, perhaps, is whether technology has evolved so that there are improved ways to meet level of assurance 3, but not lowering the standard for security and trust.

170.315(d)(2)—Auditable Events and Tamper-Resistance
We support ONC's proposal to require EHR technology to prevent all users from being able to disable the audit log through the EHR technology. This capability is central to enhancing consumers' trust.

§ 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 by patients, thereby underscoring the need for this capability. For reasons we discussed above (under Clinical Information Reconciliation and Incorporation), certified EHR technology must be able to maintain the provenance of this and other PGHD, and ONC should confirm whether the 2015 Edition must add any specifications to the 2014 Edition in order to include this functionality (provenance).

§ 170.315(d)(9) - Accounting of Disclosures
For the 2015 Edition, we recommend that ONC strengthen the audit criterion and specifications to enhance the ability to identify inappropriate access inside an entity or organized health care arrangement (OHCA). We have reviewed the recommendations on accounting of disclosures transmitted from the HIT Policy Committee and its Privacy and Security Tiger Team (dated January 22, 2014). We agree with the Tiger Team's recommendation to add two elements to the current audit control technology: (1) "audit controls must record PHI-access activities to the granularity of the user (workforce member or natural person) and the individual whose PHI is accessed" and (2)

"information recorded by the audit controls must be sufficient to support the information system activity review required by [45 CFR] §164.308(a)(1)(ii)(D) and the investigation of potentially inappropriate accesses of PHI." The 2015 Edition should incorporate these specifications as well.[19]

§ 170.315(e)(1) - View, Download, and Transmit to Third Party
Providing patients the ability to view, download, and transmit (VDT) their own health information was a monumental advancement for consumers in Stage 2 of Meaningful Use. We applaud ONC's proposals to advance many of the certification criteria to enable comprehensive and accessible health data access. Just as ONC is paying attention to usability from a provider perspective (such as in the safety-enhanced design criterion), we encourage the agency to pay similar attention to usability issues from the patient perspective in the VDT and other patient-facing criteria.

We support ONC's clarification that VDT functionality should be patient-facing, and appreciate the specific reference to authorized representatives in the criterion. Specifically granting family and other caregivers the ability to VDT patient health information reinforces their role as members of the care team, provides the essential information they need to perform their caregiver responsibilities, and supports a vision of truly person-centered care. Allowing patients to specify 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.

Patients should be able to choose in which form they would like to receive their health information. We support ONC's proposal to stress that a patient must be able to download an ambulatory or inpatient summary in whatever format the patient prefers. We also support referencing the updated C-CDA standard in this criterion.

View: We agree that it is important for patients and caregivers to have access to "implantable device information" as data made available under the "view" capability. This will also facilitate electronic exchange of UDI via VDT. ONC should also consider how best to provide patients with UDI label information and device instructions via the "view" capability.

Activity History Log: Similarly, we agree that activity history logs should record and include two new data points: the addressee to whom an ambulatory summary or inpatient summary

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[19] With respect to the accounting itself, the Tiger Team recommends pilots first to better assess the interests of the patient, any administrative burden on providers, and whether on balance proposed standards for the accounting of disclosures yield a report and information that are truly useful to patients, without overwhelming them with excessive or useless information or placing undue burden on providers. At the stage of pilots, therefore, it would be premature to recommend final criteria for the 2015 Edition.

was transmitted and whether that transmission was successful. This transaction history provides important information about care coordination that patients should be able to access.

WCAG 2.0 Level AA: We appreciate ONC's efforts to provide better access and viewing of health information for individuals with disabilities by requiring that EHR technology be compliant with Level AA. We recommend testing the system before it goes live with individuals with disabilities to ensure genuine accessibility and usability. Additionally, we encourage ONC to ensure that EHR systems are accessible for providers as well as patient populations.

Mobile Accessibility: With regard to specifying separate guidelines for mobile accessibility, we believe that accessibility should not differ depending on the mode of access and should be fully and equally integrated in all models.

2017 Edition Issues for the VDT Certification Criterion under Consideration
Images: We support ONC's intention to require that images be part of the VDT criterion, and encourage ONC to require that images be made available to patients. High-quality images are important for patients to be able to share with other providers. Excess imaging is a high-cost area, and making images available to patients is a way to reduce unnecessary costs. Furthermore, if the goal is for patients to be able to direct where to send the image, it is critical that images are able to be transmitted.

"Open Notes": To provide patients with comprehensive, transparent access to health information, we urge ONC to require that VDT criteria apply to entire medical records, including visit notes. In a quasi-experimental study of the Open Notes initiative,[20] the vast majority of participants who had access to their notes reported an increased sense of control, greater understanding of their medical issues, improved recall of their plans for care, and better preparation for future visits,[21] all of which are critical components of patient engagement. Participating providers experienced minimal impact on their workload. Furthermore, when providers were offered the option to decline further participation at the end of the intervention, none asked to stop. It is time to give patients access to *all* of their health information.

§ 170.315(e)(2) - Clinical Summary
We support ONC's proposal to reference the updated Consolidated CDA version in the

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[20] http://www.myopennotes.org/.

[21] Delbanco, T., Walker, J., Bell, S. K., Darer, J. D., Elmore, J. G., Farag, N., Feldman, H. J., Mejilla, R., Ngo, L., Ralston, J. D., Ross, S. E., Trivedi, N., Vodicka, E., Leveille, S. G., Inviting Patients to Read Their Doctors' Notes: A Quasi-experimental Study and a Look Ahead. Annals of Internal Medicine. 2012 Oct;157(7):461-470.

clinical summary certification criterion, as well as to require that EHR technology be capable of including the UDI(s) for a patient's implantable device(s) as data within the C-CDA formatted document.

§ 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 Meaningful Use. EHR technology should be capable of tracking the response to a patient-generated message (e.g., no response, secure message reply, telephone reply). We also encourage ONC to revise the language of the 2015 certification criterion to specifically allow for a patient's authorized representative to send and receive secure messages on the patient's behalf, similar to the VDT criterion. Allowing secure messages to be sent and received by a family or other caregiver approved by the patient would reinforce their essential role as members of the care team.

Furthermore, in addition to requiring the capability to track providers' responses to secure messages from their patients, we also underscore the importance of tracking the timeframe for response. We do not propose requiring a specific timeliness standard, only the measurement and reporting of timeliness rates, as is current practice for industry leaders such as Kaiser Permanente.

Looking forward to the 2017 Edition, we encourage ONC to consider adding to secure messaging the ability to provide messages in languages other than English. Appropriately implemented, 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, including with non-Meaningful Use eligible providers, like nursing homes, behavioral care, and home-based care. ONC should consider developing a voluntary certification program for LTPAC technologies used by non-meaningful use eligible providers.

2017 CEHRT Proposals
Additional Patient Data Collection
We enthusiastically support the proposal to require the collection and use of certain patient-generated data in the 2017 Edition. ONC proposes to require EHR technology to enable a user to electronically record, change, and access the data (in addition to record a patient's response as 'declined to provide'). While we appreciate ONC's attention to this critical functionality, we want to clarify that HIPAA currently gives patients the right to

submit corrections or amendments to their health information, and therefore EHR technology should already support this ability.

In addition to capturing this critical information, EHR technology should be able to electronically transmit information that was directly entered by the patient: patient-reported outcomes and patient-generated health data are an important part of their longitudinal care record. In addition to other forms of PGHD, this would also include amendments and corrections to ensure safe, high-quality care across the continuum.

We have no comment on whether to include these data elements in a new standalone or criterion or a combined certification criterion.

Disability Status & Accommodation Requests
Thank you once again for reflecting our recommendations in the Disparities Action Plan to capture information about disability status, and start with questions approved by the Data Council and promulgated by the HHS Secretary under Section 4302 of the Affordable Care to characterize functional disability. This is another area of great importance to both consumers and legislators.

We agree that health care providers could be better prepared to engage and treat patients with disabilities. We encourage ONC to consider how doctors could incorporate and benefit from this information *before* an initial visit occurs. For example, research indicates that women with physical disabilities do not receive breast cancer screenings as regularly as women without physical disabilities, often due to access issues.[22] Sometimes the breast cancer screening facilities are not accessible for women with physical disabilities, such as women in wheelchairs. Other times, the mammography equipment may not be accessible for women who have mobility issues or are unable to stand still in one position. Having patient-specific information prior to an initial visit would enable providers to be better prepared to accommodate and treat their patients.

With regard to the specific questions, we believe the questions posed by ONC are the right ones to start with. We appreciate ONC's proposal to include a field for additional comment to capture information or explanation not contained in a simple "Yes/No" response.

We recommend adding the term 'or accommodation' to references of 'special assistance' in each question, and also suggest the addition of an eighth question:

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[22] Barr JK, Giannotti TE, Van Hoof TJ, Mongoven J, and Curry M. Understanding barriers to participation in mammography by women with disabilities. Am J Health Promot. 2008 Jul-Aug;22(6):381-5. doi: 10.4278/ajhp.22.6.381.

1. Are you deaf or do you have difficulty hearing? If so, what special assistance **or accommodation** may you need?
2. Are you blind or do you have difficulty seeing, even when wearing glasses? If so, what assistance **or accommodation** may you need?
3. Because of a physical, mental, or emotional condition, do you have serious difficulty **understanding** concentrating, remembering, or making decisions? (patients 5 years old or older). If so, what assistance **or accommodation** may you need?
4. Do you have difficulty walking or climbing stairs? (patients 5 years old or older) If so, what assistance **or accommodation** may you need?
5. Do you have difficulty dressing or bathing? (patients 5 years old or older). If so, what assistance **or accommodation** may you need?
6. Because of a physical, mental, or emotional condition, do you have difficulty doing errands alone such as visiting a doctor's office or shopping? (patients 15 years old or older). If so, what assistance **or accommodation** may you need?
7. Do you have difficulty **understanding**, communicating, reading, or do you have limited proficiency in English **(i.e., American Sign Language, ASL speaker**)? If so, what assistance **or accommodation** may you need?
****8. Do you have a person assisting you in your daily living (e.g., personal care attendant)?**

Requiring the functionality to collect disability status information and requests for specific accommodations is entirely appropriate; this is crucial, clinically-relevant information that needs not only to be captured, but exchanged among multiple health care providers. If a disabled individual receives a referral to a specialist from her primary care provider, the patient and specialist would benefit from having disability status and accommodation information ahead of time (to help ensure, for example, that the specialist's exam room is equipped with an accessible exam table, or additional appointment time is scheduled to accommodate a patient's cognitive impairment). This is particularly important as recent research indicates that patients with disabilities have difficulties when trying to access specialty care.[23] Ultimately, the health care system must be accessible to all patients, and certified EHR technology can help capture and exchange critical information to ensure that suitable accommodations are made for all patients.

Sexual Orientation (SO)/Gender Identity (GI)
We thoroughly agree that EHR technology should be capable of electronically recording, changing, and accessing data on a patient's sexual orientation and gender identity. We appreciate that ONC incorporated the SO/GI recommendations presented in the

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[23] Lagu T, Hannon NS, Rothberg MB, Wells AS, Green KL, Windom MO, Dempsey KR, Pekow PS, Avrunin JS, Chen A, and Lindenauer PK. Access to subspecialty care for patients with mobility impairment: A survey. Annals of Internal Medicine. 2013 Mar;158(6):441-446.

Disparities Action Plan. The congressional and consumer letters to ONC and CMS also advocated for the collection of sexual orientation and gender identity data, and encouraged ONC to require all certified EHR technology to have the functional capacity to collect this information.

Patients' SO/GI health information has clinical relevance and is vital for improving health outcomes. For example, transgender individuals have increased risk for certain health conditions, such as depression, suicide, and HIV, and frequently do not receive appropriate "gendered" preventive screenings such as Pap tests, mammograms, and prostate exams. Additionally, studies have shown that lesbians and bisexual women are less likely to receive Pap tests and cervical cancer screenings than heterosexual women, and that gay and bisexual men have a higher prevalence of sexually transmitted infections (STIs), including HIV.[24] Allowing providers to collect and store patients' SO/GI data in their EHRs would ensure that patients receive appropriate care specific to their individual needs.

While we strongly support the intent behind it, we are agnostic with regard to the specific code sets used to capture SO/GI information in a structured format. However, while the SNOMED code sets are a good starting place, they do not fully capture the entire spectrum of sexual orientation and gender identity. For example, we suggest adding "other" and "unsure" as categories for sexual orientation. We recommend that ONC look to the work of organizations such as The Fenway Institute and Center for American Progress, which have published extensive studies on successful methods for SO/GI data collection.[25] Recently, they successfully collected sexual orientation and gender identity data from patients in four health care centers across the country using the following gender identity categories: male; female; female-to-male/transgender male/trans man; male-to-female/transgender female/trans woman; gender/queer, neither exclusively male nor female; additional gender category/other/please specify; and decline to answer.

As ONC notes, there have been privacy and security concerns about the collection of SO/GI data. While patients' privacy is always of the upmost importance, a balanced approach allows providers to ask necessary questions about sexual orientation and gender identity and allows patients to self-disclose while ensuring that privacy is protected. This information is critical not only for providers, but also for clinical staff in order to provide culturally competent service. We encourage ONC to work with LGBT health organizations to find the right balance to assure patients' privacy and meet their health care needs.

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[24] 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. 2013.
[25] Ibid.

U.S. Military Service
We agree that information on U.S. Military service has clinical relevance and is important to capture in certified EHR technology.

Work Information – Industry/Occupation
We agree that industry/occupation information has clinical relevance and is important to capture. Industry/occupation information is particularly important for underserved populations who work jobs with significant risks and environmental hazards that have implications for adverse health outcomes.

Medication History
We support the proposal to add a certification criterion focused on medication history capabilities for the 2017 Edition. Medication history is important information that should be available to both patients and providers. This capability is particularly important given that 76 percent of Americans over age 60 take two or more prescription drugs and 37 percent take five or more. This information should also be made available to patients through VDT.

Blue Button +
We are very supportive of Blue Button Plus, which provides an easy way for patients to direct their records to another location of their choosing. This functionality will be particularly important to realize consumers' vision of the next generation of dynamic, multifaceted care plans built on an electronic platform. In 2013, the National Partnership released a report detailing consumer priorities for health and care planning (cited above); we encourage ONC to draw upon this report as a resource.

Duplicate Patient Records
We applaud efforts to better identify and correct duplicate records. As we explained above (transitions of care), patient matching must take into account the diverse characteristics and attitudes among patient populations and be designed accordingly. We recommend that ONC consider pilots to study the effectiveness of various approaches to improve accuracy with the data we use today. We recommend concurrent educational efforts that emphasize the importance of accurate patient identification and matching for improving patient safety.

K. Certification of Other Types of HIT and for Specific Types of Health Care Settings
Children's EHR Format
We appreciate ONC's recognition of the need to identify, and include as appropriate, a core set of standardized pediatric data elements to support the care of children. We encourage ONC to build upon the previous efforts of HHS to define elements of a pediatric EHR.

Practice Transformation

We are very excited to see ONC propose certification criteria that focus on advanced care coordination features to integrate a patient's care plan into visit screens for the provider, as well as a patient view of the care plan that displays an updated and modifiable care plan documentation field.

We envision the next generation of care plans built on an electronic platform that connects individuals, their family and other personal caregivers, paid caregivers (such as home health aides), and health care and social service providers, as appropriate, and provides actionable information to identify and achieve the individual's health and wellness goals. Ideally, care plans should also enable patient access and ability to contribute and correct health information (such as family health history, goals, chosen support individuals and networks, and advance directive content) to help manage their care and wellbeing. The advanced care coordination functionality being proposed by ONC would make significant progress toward realizing this vision.

Thank you once again for the opportunity to provide input into the proposed 2015 Edition of certified EHR technology. We are enthusiastic about the value consumers, specifically, will see as these criteria are implemented.

Sincerely,

AARP
American Association of Birth Centers
American Association on Health and
  Disability
American Federation of State, County
  and Municipal Employees
American Heart Association / American
  Stroke Association
Asian & Pacific Islander American
  Health Forum
Association of Asian Pacific Community
  Health Organizations
Bechtel Health
California Center for Rural Policy
Center for Democracy & Technology
Community Action Partnership
Consumers Union
Disability Policy Consortium
Family Caregiver Advocacy

Disability Rights Education and Defense
  Fund
Fenway Institute
Futures Without Violence
Healthwise, Inc.
Health Access California
Informed Medical Decision Making
  Foundation
National Consumers League
National Council of La Raza
National Health Law Program
National Senior Citizens Law Center
National Partnership for Women &
  Families
Summit Health Institute for Research
  and Education, Inc.
The Arc of the United States
The Children's Partnership
MaryAnne Sterling, Family Caregiver
  Advocate