Consumer
Partnership
for eHealth

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Submitted electronically

Dr. Karen DeSalvo, M.D., M.P.H., M.Sc.
National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Avenue SW, Suite 729D
Washington, D.C. 20201

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

re: Consumer Partnership for eHealth's Comments on Proposed Rulemaking – RIN 0991-AB93 – 2015 Edition Health Information Technology Certification Criteria

Dear Dr. DeSalvo:

The Consumer Partnership for eHealth (CPeH) and the undersigned 30 organizations and individuals[1] submit these formal comments on the proposed 2015 Edition Health Information Technology Criteria. The Consumer Partnership for eHealth (CPeH) is a coalition of consumer, patient and labor organizations working since 2005 at the national, state and local levels to advance electronic health information technology and exchange (health IT) in ways that measurably improve the lives of individuals and families. Led by the National Partnership for Women & Families, the combined membership of CPeH represents more than 127 million Americans. Consumers are eager to work with the Office of the National Coordinator for Health Information Technology (ONC) to achieve a nationwide health ecosystem for the benefit of all Americans, and we thank you for the opportunity to provide these comments on the notice of proposed rulemaking (NPRM).

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 clearly reflect a commitment to meeting the needs of patients and families. Collectively they 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 health IT broadly, they extend the benefits to patients and families in long-term and post-acute care settings, in behavioral health settings, in pediatric settings. They facilitate the movement towards patient-centered care through capture of critical information about individuals' health and care outside the clinical setting (e.g. 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 consistent with CPeH's Disparities Action Plan[2] and Care Plans 2.0 report.[3] The reader is sometimes left wishing that the important new

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[1] The 30 organizations and members of the Consumer Partnership for eHealth, joined by others, who sign this letter do so jointly in one letter rather than send 30 separate letters. If ONC counts responses for any particular purpose, please count them as 30 responses rather than a single response.

[2] *Leveraging Meaningful Use to Reduce Health Disparities: An Action Plan* (Aug. 2013), available at http://www.nationalpartnership.org/research-library/health-care/HIT/leveraging-meaningful-use-to.pdf.

[3] *Care Plans 2.0: Consumer Principles for Health and Care Planning in an Electronic Environment* (Nov. 2013), available at http://www.nationalpartnership.org/research-library/health-care/HIT/consumer-principles-for-1.pdf.

capability was paired with a complementary policy requirement that providers use it meaningfully to benefit patients—for example, the 2015 edition's capability to request patient-specific education materials in the patient's preferred language, but 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 affects individuals, patients,[4] family caregivers and communities across America. Defining the "Care Plans" criterion to include patients' goals, and patients' and family caregivers' health concerns, greatly improves the relevant health information available to providers, patients and family caregivers for shared decision-making. Defining the "Demographics" criterion to include race and ethnicity at the Institute of Medicine's recommended level of granularity markedly improves the ability of the entire learning health system to identify, understand and reduce health disparities. Introducing "Application Access to Common Clinical Data Set" should improve individuals' access to and use of their health information, whenever and wherever needed. Conversely, neglecting to include sexual orientation and gender identity, and disability status, in the Common Clinical Data Set misses a critical opportunity to substantially improve care and reduce disparities for approximately 9 million[5] and 56 million[6] Americans respectively.

Our comments on specific proposals follow. While we have not commented on other 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. Additionally, many items that we discuss below, such as health disparities and social, psychological, and behavioral data, as well as disability status, all have public health implications.

§ 170.102—Common Clinical Data Set

The Consumer Partnership appreciates 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.**

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[4] For brevity, we refer throughout our comments to "patient" and "care," given that many federal programs and initiatives are rooted in the medical model. To some, these terms could imply a focus on episodes of illness and exclusive dependency on professionals. Any effort to improve patient and family engagement must include the use of terminology that also resonates with the numerous consumer perspectives not adequately reflected by medical model terminology. For example, people with disabilities frequently refer to themselves as "consumers" or merely "persons" (rather than patients). Similarly, the health care community uses the terminology "caregivers" and "care plans," while the independent living movement may refer to "peer support" and "integrated person-centered planning."

[5] Gary Gates & Frank Newport, Williams Inst., Univ. of Cal. Los Angeles Sch. of Law, *Gallup Special Report: New Estimates of the LGBT Population in the United States* (2013), available at http://williamsinstitute.law.ucla.edu/research/census-lgbt-demographics-studies/gallup-lgbt-pop-feb-2013/.

[6] U.S. Census Bureau, *Americans with Disabilities: 2010*, at 4, 8-9, 17-19 (2012), available at http://www.census.gov/prod/2012pubs/p70-131.pdf%20.

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, and the NPRM neglects to include that in the Common Clinical Data Set here.

As proposed, the Common Clinical Data Set does not include sexual orientation and gender identity, nor disability status. We urge ONC to incorporate both.

a. Disability status, cognitive status and functional status.

Patients' disability status, including cognitive status and functional limitations, is crucial, clinically-relevant information that must be captured and exchanged among multiple health care providers. ONC proposes to include cognitive status and functional status in the "Transitions of Care" criterion and the "Data Portability" criterion, but including patients' disability status in the common clinical data set will help to ensure that all patients receive appropriate care specific to their individual needs, and thereby help to reduce health disparities.[7] Furthermore, we encourage ONC to capture more granular data about specific disability status and functional limitations, not a simple "yes/no" question regarding disability.[8] To this end, we repeat comments we submitted to ONC in response to its Voluntary 2015 Edition NPRM published on February 26, 2014.

We agreed with ONC there that health care providers could and should be better prepared to engage and treat patients with disabilities, and we agree that the specific questions posed by ONC are the right ones to start, including a field for additional comment to capture information or explanation not contained in a simple "Yes/No" response. We recommend adding "or accommodation" in each question, and also suggest the addition of an eighth question:

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?

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[7] T. Lagu, N.S. Hannon, M.B. Rothberg, A.S. Wells, K.L. Green, M.O. Windom, K.R. Dempsey, P.S. Pekow, J.S. Avrunin, A. Chen & P.K. Lindenauer, *Access to subspecialty care for patients with mobility impairment: A survey*, 158 Annals of Internal Medicine 441 (Mar. 2013).

[8] The American Community Survey, administered by the US Census Bureau, uses six questions related to disability that have been well-researched and validated. M. Brault, U.S. Census Bureau, *Review of Changes to the Measurement of Disability in the 2008 American Community Survey* (Sept. 2009), available at http://www.census.gov/people/disability/files/2008ACS_disability.pdf.

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 capability to collect disability status information and requests for specific accommodations is crucial, clinically-relevant information that is also needed for equal treatment. If a person with a disability 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.[9] **The issue and benefits are not just limited to transitions of care; they are common to all settings, and thus incorporation in the Common Clinical Data Set is ideal.**

b. Sexual orientation/gender identity (SO/GI).

Patients' sexual orientation and gender identity are clinically relevant and 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.[10] **Providers should collect and integrate patients' sexual orientation and gender identity in order to ensure that patients receive appropriate care specific to their individual needs.**

The NPRM proposes to include sexual orientation and gender identity in the optional "Social, Psychological, and Behavioral Data" criterion. Like disability status, this health information is *essential*, not optional, for appropriate care across all settings and should be incorporated in the Common Clinical Data Set.

§ 170.315(a)(5)—Demographics

The NPRM proposes to improve standards for race and ethnicity and preferred language in the "Demographics" criterion and by extension in the Common Clinical Data Set. CPeH applauds both important improvements.

- ***Race and ethnicity***

The 2014 Edition requires collection of race and ethnicity based on the standards created by the Office of Management and Budget (OMB). These standards provide a minimal set of just six broad categories for race and ethnicity. In 2009, the Institute of Medicine (IOM)

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[9] T. Lagu, N.S. Hannon, M.B. Rothberg, A.S. Wells, K.L. Green, M.O. Windom, K.R. Dempsey, P.S. Pekow, J.S. Avrunin, A. Chen & P.K. Lindenauer, *Access to subspecialty care for patients with mobility impairment: A survey*, 158 Annals of Internal Medicine 441 (Mar. 2013).

[10] The Fenway Institute & Center for American Progress, *Asking patients questions about sexual orientation and gender identity in clinical settings: A study in four health centers* (2013), available at http://thefenwayinstitute.org/wp-content/uploads/COM228_SOGI_CHARN_WhitePaper.pdf.

recommended much more granular data collection standards reflecting the populations served in different communities.[11] The NPRM proposes to add the capability to record each one of a patient's races and ethnicities in accordance with the "Race & Ethnicity—CDC" code system, which is the current equivalent of the standards IOM discussed in 2009 and can be "rolled-up" into the OMB standard.

This will facilitate significant improvements in health care and identifying health disparities. 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.[12]

There is widespread agreement that identification and elimination of health disparities should be a national priority. Not only did CPeH's 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 to ONC and the Centers for Medicare & Medicaid Services (CMS). **We understand why this NPRM is silent on *how* providers must use this capability, but we underscore that complementary policy regulations (namely Meaningful Use) should not be silent on *whether* providers appropriately use the function and capture this granular demographic information.** In order to reduce health disparities, providers, individuals and communities, public health officials and researchers need the better understandings and tools that the CDC code set enables.

- ***Preferred language***

We strongly support recording all languages preferred by the patient, including written, spoken, and signed languages and dialects. Identification and use of a patient's preferred language, whatever it is (American Sign Language for deaf individuals or Hmong, for example), 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. To that end, we support ONC's adoption of the widespread and more inclusive RFC 5646 standard.

§ 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 to request patient-specific education resources based on preferred language. Given that clinical decision support is a primary means of providing best evidence and knowledge at the point and time of care, that is the prime moment to request patient-specific education resources in the patient's preferred language.

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[11] Institute of Medicine, *Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement* (Aug. 2009), available at http://www.iom.edu/~/media/Files/Report%20Files/2009/RaceEthnicityData/Race%20Ethnicity%20report%20brief%20FINAL%20for%20web.pdf.

[12] P.M. Barnes, P.F. Adams & E. Powell-Griner, *Health Characteristics of the Asian Adult Population: United States, 2004-2006*, 394 Adv. Data. 1 (Jan. 22, 2008).

For similar reasons, we repeat two comments in response to questions ONC raised in the prior Voluntary 2015 Edition NPRM published on February 26, 2014. There, ONC proposed to include the capability to activate CDS interventions using at least one of the "demographics" data categories (e.g. sex or date of birth). We urge again that clinical decision support be able to use *at least two* of the demographic data elements (e.g. race or ethnicity and sex, or sex and cause of death). As CPeH noted in its Disparities Action Plan, this is critical functionality; 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.

In addition, our comments there urged ONC to include family health history in the data categories for the CDS criterion. Adding family health history to CDS rules could provide pertinent clinical information, and could also strengthen and improve the standards for family health history.

§ 170.315(a)(16)—Patient List Creation

We support the proposal to require Health IT Modules to demonstrate capability to use each one and at least one combination of the specified data categories, including elements in the "Demographics" 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 here constitutes that much-needed progress from the first two stages of Meaningful Use, which required providers to record patients' demographic information and to generate at least one list of patients by specific condition.

The ability to filter or stratify patient lists by disparity variables such as race, ethnicity, language, gender identity, sexual orientation or disability status 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 might 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.[13] **Again, we urge ONC to require capability to use *at least two* demographic data elements to generate patient lists.** This would help 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.

ONC should also include a minimum list of patient communication preferences that every EHR should be able to make available, as it flagged in the Voluntary 2015 Edition NPRM. We recommend that preferences include electronically through secure email or a patient portal, paper through regular mail, telephone, and text—as well as alternate format renderings, such as large font and audio. Paper remains relevant even if Stage 3 focuses on electronic means, because the 2015 Edition extends to health IT, not just EHRs for Meaningful Use, and paper materials remain important for some patients.

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[13] Hospitals in Pursuit of Excellence, *Reducing health care disparities: Collection and use of race, ethnicity and language data* (Aug. 2013), available at http://www.hpoe.org/resources/hpoehretaha-guides/1431.

§ 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. 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.[14] EHRs should be able to provide 100 percent of education resources in Spanish, if not the top five languages nationally. When ONC raised this question in its Voluntary 2015 Edition NPRM, developers did not support a proposal to provide in *all* preferred languages due to the burden they stated it would create because of the great number of potential languages and the lack of content resources for all potential languages. Providing the resources in just the top five languages nationally, or at least Spanish, addresses 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 individuals' and patients' care preferences, from birth plans to advance directives. This necessarily broadens the age range as well, as patient health information documents such as birth plans occur much earlier than age 65.

We support as well ONC's proposal to make this criterion much more useful by adding the capability to store and access the document, and include information on where to locate it, e.g. by link to the document or instructions regarding 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 according to 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.

§ 170.315(a)(20)—Implantable Device List

We support the capture and exchange of an implantable device list through the Common Clinical Data Set as the 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, and improve patient safety. This new criterion strengthens patients' access to information about what devices are in their bodies, makes it easier to share that

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[14] U.S. Census Bureau, *Language Use in the United States: 2011*, p. 3 (Aug. 2013), available at https://www.census.gov/prod/2013pubs/acs-22.pdf.

information with the patients' various healthcare providers, and enables consumers and providers to be vigilant to alerts and recalls for the duration of their device. Indeed, at some point this capability might be coupled with a national implantable device registry.

ONC does not propose at this time to include automatic identification and data capture (AIDC) technology to record the unique device identifier (UDI). The fact remains that such technology would prevent human error in typing lengthy serial numbers, etc.—the very type of medical error that UDIs and implantable device lists are intended to prevent. We urge ONC to incorporate this kind of capability. We also urge ONC to consider how best to access and integrate other important data beyond the "Device Description." As ONC notes, access to information such as MRI-compatibility and latex content at the point of care is likewise important and can prevent adverse medical errors and events.

§ 170.315(a)(21)—Social, Psychological, and Behavioral Data

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.[15] 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 and community-based health organizations, including those serving persons with disabilities. **We applaud ONC's addition of a new capability to capture and integrate data on social, psychological, and behavioral determinants of health.** 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.

Standardized collection of such data 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 this end, we appreciate the recognition that data on social, psychological, and behavioral determinants are key types of patient-generated health data to be included in fulfilling Objective 6 of Stage 3 of Meaningful Use.

a. ***Standardized questions on sexual orientation and gender identity.***

While we have urged above that patients' sexual orientation and gender identity data be included in the Common Clinical Data Set, we commend ONC for including sexual orientation and gender identity in this criterion for the same reasons.

The codes may be functional and the best available, but the associated terms are outdated or even offensive to some people in some cases, and further work is needed. 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 questions and methods for collecting SO/GI data.[16]

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[15] 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.

[16] The Fenway Institute & Center for American Progress, *Asking patients questions about sexual orientation and gender identity in clinical settings: A study in four health centers* (2013), available at http://thefenwayinstitute.org/wp-content/uploads/COM228_SOGI_CHARN_WhitePaper.pdf.

b. *Work information—industry/occupation data.*

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

§ 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. These new elements can also support efforts, for example, to ensure that persons with disabilities receive and use services in the most integrated setting appropriate to their needs.

- ***Patient matching.***

In prior comments, CPeH has recommended that ONC consider 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. Therefore, ONC should standardize the individual patient matching characteristics, but should also choose the set of characteristics that works best across the range of patient populations, taking into account ethnic and cultural differences. The NPRM does not indicate whether ONC considered this need for balance, so we urge the point again.

In addition, 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 sex may change throughout the course of a person's lifetime, the sex assigned at birth will not, and is therefore better suited for patient matching efforts. Because of the realities of gender identity, the criterion should use the HL7 Version 3 "Natal Sex" measure rather than AHRQ "Administrative Gender" measure to capture sex.

§ 170.315(b)(6)—Data Portability

For reasons we have set forth above, we agree with ONC's inclusion of the Common Clinical Data Set, and functional and cognitive status, in the "Data Portability" criterion for providers. We also suggest that ONC include clinical notes—initially surgical and treatment notes for inpatient settings and visit notes for ambulatory settings.[17] Lastly, we support the ability to filter these data by date and time and to include at least three years of data for patients, which permits exporting a more longitudinal record.

§ 170.315(b)(7), § 170.315(b)(8)—Data Segmentation for Privacy

We appreciate this initial step and endorse the proposal to adopt EHR certification criteria that enable patients or providers to electronically share parts, but not all, of a patient

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[17] We acknowledge that HIPAA and many state laws separately regulate the disclosure of especially sensitive health information such as psychiatric clinical notes, and might include different requirements.

record, especially health information covered by 42 CFR part 2. We agree with some of the concerns deliberated by the Privacy and Security Workgroup, especially segmentation and tagging at the document level, not the data level. Further work and innovation are needed; yet we must move forward, and this approach to the send and receive functions is a workable step forward.

§ 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.[18]

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.

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 percent) 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.[19]

§ 170.315(c)(4)—Clinical Quality Measures – Filter

We strongly support ONC's proposal to require that health IT be able to filter clinical quality measure (CQM) results to create and stratify different patient population groupings by such variables as sex, race and ethnicity, and patient problem list. This capability is critically important to identify and address health disparities and gaps in care, as CPeH discussed in its Disparities Action Plan and as Members of Congress urged in letters to ONC and CMS regarding health disparities. We agree that the criterion should filter at both the individual patient level and aggregate levels, including particular group practice sites and accountable care organizations (ACOs).

We appreciate ONC's progress in requiring that the Health IT Module be able to filter by any one or any combination of the specified variables. The use of multiple demographics variables in the filtering of CQMs would allow providers to more accurately reflect the care and experiences of the full range of patients and thus identify health disparities. It is essential that

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[18] *Care Plans 2.0: Consumer Principles for Health and Care Planning in an Electronic Environment* (Nov. 2013), available at http://www.nationalpartnership.org/research-library/health-care/HIT/consumer-principles-for-1.pdf.

[19] National Partnership for Women & Families, *Engaging Patients and Families: How Consumers Value and Use Health IT*, p. 37 (Dec. 2014), available at http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf.

providers utilize the improved granularity of race and ethnicity data to filter CQMs in order to effectively work to reduce health disparities.

We encourage ONC to broaden the list of variables required for filtering to include preferred language—included in the proposed requirements for the voluntary 2015 edition—as well as data on sexual orientation, gender identity, disability status, functional status, and cognitive status.

§ 170.315(d)(1)—Authentication, Access Control, and Authorization

For the 2015 Edition, we repeat comments we submitted on the Voluntary 2015 Edition NPRM. 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 agree with the Tiger Team's 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 helps to meet that need. For future certification requirements, ONC should remain abreast of technological developments that enable authentication at level of assurance 3 in ways that fit with provider workflows, consistent with the Tiger Team's recommendations.

§ 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 prevent all users from being able to disable the audit log through the EHR technology to enhance consumer 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. 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).

§ 170.315(d)(9)—Accounting of Disclosures

For the 2015 Edition, we repeat our recommendations on the Voluntary 2015 Edition NPRM, that ONC should strengthen the audit criterion and specifications to enhance the ability to identify inappropriate access inside an entity or organized health care arrangement (OHCA). 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.[20]

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

The Consumer Partnership appreciates ONC's proposed clarification that the View/Download/Transmit functionality should be patient-facing, and appreciates the specific reference to authorized representatives in the criterion. **Specifically granting family and other caregivers the ability to view, download and transmit 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.** In the National Partnership's recent nationwide survey, 87 percent of patients reported that online access to a family member's health information would help them with their caregiving responsibilities.[21]

We appreciate and support as well the inclusion of access to the Common Clinical Data Set, the updated Consolidated CDA and diagnostic image reports. We have already covered elsewhere the importance of the Common Clinical Data Set and the care planning and coordination benefits of the C-CDA.

ONC asks whether the criterion should make additional data available to patients, including functional status and cognitive status. We agree that functional status should be made available, but caution ONC on including cognitive status without additional consideration of potential safety and privacy risks, especially when sharing these data might serve as a trigger for those who have a potential to inflict harm on themselves or others. Perhaps the provider's authority pursuant to the HIPAA Privacy Rule, 45 CFR § 164.524, to restrict access in cases of psychotherapy notes or substantial harm to the individual provide sufficient safety, but this warrants consideration.

We also recommend that "View, Download, and Transmit" criterion 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 be available as well.

We very much appreciate ONC's efforts to provide better access and viewing of health information for individuals with disabilities, and we recommend requiring that this criterion 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 and health IT are accessible for providers as well as patient populations.

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[20] 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.

[21] National Partnership for Women & Families, *Engaging Patients and Families: How Consumers Value and Use Health IT*, p. 37 (Dec. 2014), available at http://www.nationalpartnership.org/research-library/health-care/HIT/engaging-patients-and-families.pdf.

§ 170.315(e)(2)—Secure Messaging

In the National Partnership for Women & Families' recent survey, a majority of patients nationwide (56 percent) wanted the ability to email their providers.[22] 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 (e.g., no response, secure message reply, telephone reply). Similarly, health IT should be capable 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.

Finally, we strongly encourage ONC to consider adding to secure messaging the ability to send and receive secure messages in languages other than English. Appropriately implemented, this functionality could be the key to improved communication between patients and providers, improved health outcomes and reduced errors.

§ 170.315(g)(5)—Accessibility Technology Compatibility

We strongly agree that health IT should be accessible to users regardless of their visual impairments or disabilities, and appreciate and support ONC's addition of this new criterion. We agree that the criterion would likely serve as a valuable market distinction for health IT developers and consumers. However, demonstrating compatibility with just one accessibility technology is not sufficient to meet the multiple disabilities of over 56 million individuals across the nation. Therefore, we encourage ONC to strengthen this criterion in future updates to the certification criteria.

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

The Consumer Partnership 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" criterion 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 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(g)(8)—Accessibility-Centered Design

We appreciate and support this criterion, especially for its potential to encourage health IT developers to apply and comply with more accessibility standards and laws in product development. Millions of people across the country depend upon it.

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[22] Id., p. 34.

§ 170.556—"In-the-field" Surveillance Decertification

Post-market surveillance is necessary to ensure that EHRs (including patient portals and APIs) function for providers and patients in the real world as they perform in the certification laboratory. Decertification must be among the tools and remedies available to ONC in appropriate cases, as enabled by additional rulemaking.

Thank you once again for this opportunity to provide input to ONC's proposed 2015 Edition Health Information Technology Criteria and the significant role they can play in achieving an interoperable health IT infrastructure and learning health system capable of patient- and family-centered care and true delivery system reform. If you have any thoughts or questions about these comments, please contact Mark Savage at (202) 986-2600 or MSavage@nationalpartnership.org.

Sincerely,

AARP
Association of Asian-Pacific Community Health Organizations
American Association on Health & Disability
American Cancer Society Cancer Action Network
Asian & Pacific Islander American Health Forum
Caring From a Distance
Center for Democracy & Technology
Consumers' Checkbook/Center for the Study of Services
Disability Rights Education and Defense Fund (DREDF)
Families USA
Family Caregiver Advocacy
Fenway Health
Genetic Alliance
Hannah's Hope Fund
Healthwise
Hermansky-Pudlak Syndrome Network
Informed Medical Decisions Foundation
MLD Foundation
National Consumers League
National Council of La Raza
National Health IT Collaborative for the Underserved
National Health Law Program
National Partnership for Women & Families
PXE International
RASopathies Network USA
Service Employees International Union
The Children's Partnership
The Fenway Institute
Universal Health Care Action Network of Ohio
MaryAnne Sterling

cc: The Honorable Sylvia Matthews Burwell
Secretary, Department of Health and Human Services
Acting Administrator Andy Slavitt
Centers for Medicare & Medicaid Services