Consumer-Purchaser
ALLIANCE
Better information. Better decisions. Better health care.

May 29, 2015

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National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
200 Independence Ave. SW, Suite 729D
Washington, DC 20201

RE: Consumer-Purchaser Alliance comments on 2015 Certified Health Information Technology proposed rule

Dear Dr. DeSalvo,

The 16 undersigned organizations representing consumer and purchaser interests appreciate the opportunity to comment on the proposed rule for the 2015 Edition of Certified Health Information Technology and 2015 Edition Base Electronic Health Record (EHR) Definition. The Consumer-Purchaser Alliance (C-P Alliance) is a collaboration of leading consumer, purchaser, and labor organizations committed to improving quality and affordability of health care through the use of performance information to inform consumer choice, payment and quality improvement. The proposed rule includes a number of important changes to improve the information infrastructure underlying the health system during a time of rapid change toward models of care and payment that produce and reward value.

The collective vision of the C-P Alliance is a future in which we have meaningful and useful measures of performance, including clinical and person-reported outcomes, coordination of care, affordability, and patient experience of care[1]. Such information can be used by consumers to make informed choices about their health care, by purchasers to make good decisions about the health benefits they offer, and by physicians, hospitals, and other health care providers to continuously improve the care they deliver. Critical to achieving this vision is a robust and effective health information infrastructure that streamlines the efficient collection, sharing, and use of health information by the full continuum of health

[1] 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."

system participants and stakeholders. In the same vein, a learning health system relies on information access by and flow between all health system participants and stakeholders. While patient-provider interoperability is not directly addressed by this proposed rule, we urge ONC to consider this critical information channel in the further development of certification standards for the information infrastructure underlying our health system.

We applaud CMS and ONC for recognizing that the manifestation of health care providers as "Meaningful Users" of health IT must evolve with technology. The original concept that meaningful use would only apply to EHRs is outmoded, and the certification and incentive programs must adapt to include a wide array of health technologies and information users. We commend ONC for adapting the Certification program to apply to more types of health IT while improving the criteria for this technology to better support a high value health care system. The proposed regulations are a very important step in the effort to ensure that health IT facilitates better care, better health, and better value, and they 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 of robust information systems to patients and families in a wide variety of settings beyond hospitals and doctors' offices, and to other health system stakeholders who need comprehensive information about health system performance. The regulations facilitate the movement toward patient-centered care through capture of critical information about individuals' health and care outside the traditional 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). The 2015 Certification proposed rule and its technology-inclusive perspective will further a multifaceted information system that supports the three-part aim of better care, better health, and lower costs.

Below are our comments on specific sections of the proposed rule, numbered to match the template for public comments provided by ONC.

§ 170.102—Common Clinical Data Set

The draft Nationwide Interoperability Roadmap articulates the need for a common clinical data set, and establishes an immediate goal for 2015-2017 that individuals and providers can send, receive, find and use a common clinical data set to improve health and health care quality.[2] Thus defining that set correctly and ensuring that all essential data are included is especially important.

We appreciate ONC's effort here to define that common set of clinical data for certified 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-

[2] Office of the National Coordinator for Health Information Technology, Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap, pp. 11-13 (Jan. 30, 2015) (draft ver. 1.0).

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 and truly person-centered care.

§ 170.315(a)(5)—Demographics

The NPRM proposes to improve standards for demographics including more granular race and ethnicity information in the "Demographics" criterion and by extension in the Common Clinical Data Set. C-P Alliance applauds this important improvement. These changes will support identification of problematic disparities in the health system and better links between care provided and health outcomes. 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.[3]

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. This granular information is critical to public health research as well as provider performance measurement.

§ 170.315(a)(19)—Patient Health Information Capture

We strongly support the proposal to expand the patient health information capture requirement 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 also support the proposal to make the criterion more useful by adding the capability to store and access the document, and include information on where to locate it. The proposed criterion has the potential to support a coordinated view of care across multiple sites, providers, and episodes of care, and to integrate that view with the patient's currently active health issues, future goals, and expectations.

§ 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. We also support the

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[3] Wang EJ, Wong EC, Dixit AA, Fortmann SP, Linde RB, Palaniappan LP. Type 2 Diabetes: Identifying High Risk Asian American Subgroups in a Clinical Population. *Diabetes Research and Clinical Practice*. 2011; 93(2):248-54. doi: 10.1016/j.diabres.2011.05.025

provisions that would enable health IT modules to extract information about the device from FDA's Global Unique Device Identifier Database (GUDID) into the record. This new criterion strengthens patients' access to information about what devices are in their bodies, makes it easier to share that information with the patients' various healthcare providers, and enables consumers to be vigilant to alerts and recalls for the duration of their device.

To maximize the benefit of this new criterion, we suggest two changes. First, we are concerned that the proposed rule does not require any form of automatic identification and data capture (AIDC) capabilities to record the unique device identifier (UDI). There is potential for UDIs to be several dozen digits in length; failure to support some form of AIDC capabilities will require providers to manually enter the information, increasing the chances of an error and discouraging clinicians from documenting the devices implanted in the patient. In harmony with FDA's requirement that medical device labels include at least one form of AIDC capability, ONC should require EHRs to also support at least one form of automated UDI capture.

Second, ONC proposes to extract only the "Device Description" field from FDA's GUDID. Unfortunately, this field is voluntary and unstandardized, potentially leading to the lack of critical human-readable information contained in the EHR. Instead, ONC should require EHRs to extract information from mandatory and standard GUDID fields, including those that describe the manufacturer, model, size and MRI-compatibility of the implant.

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

We applaud ONC's addition of a new capability to capture and integrate data on social, psychological, and behavioral factors that influence an individual's health. Social and behavioral information complements clinical information and is critical to achieving the Triple Aim of better care, better health, and lower costs. In addition, person-generated health data, person-reported functional status, and person-reported outcomes are critical to personalizing care to best fit an individual, and to developing and using high-value performance measures. In particular, we are very pleased to see the inclusion of the two-item Patient Health Questionnaire 2 item (PHQ-2) in the list of questions proposed for the 2015 Edition Certification requirements. The PHQ-2 is a validated depression screening tool that can help identify individuals who should have follow-up diagnostic testing. Overall, we commend ONC on adopting the panel of measures recommended by the IOM Committee on Recommended Social and Behavioral Domains and Measures for Electronic Health Records.[4]

Standardized collection of social, psychological, and behavioral data has important implications for patient-generated health data, because in many instances patients will be the best source of information about 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. These data are critical for a learning health system and for demonstrating that the health system can deliver on what matters most: improved health outcomes and functional status.

[4] Adler NE, Stead WW. Patients in Context—EHR Capture of Social and Behavioral Determinants of Health. *New England Journal of Medicine*. 2015; 372:698-701. doi: 10.1056/NEJMp1413945

§ 170.315(b)(1)—Transitions of Care

We appreciate and support ONC's proposal to adopt the updated Consolidated Clinical Document Architecture (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 data are essential to maintaining person-centered care and to supporting shared decision-making, and a coordinated transition of care must be informed by a complete record that includes this information.

We acknowledge that the proposal to require certified health IT to send and receive both C-CDA Release 1.1 and C-CDA Release 2.0 may be somewhat burdensome to providers. However, we agree with ONC's perspective that this approach is a way to mitigate the potential interoperability challenges as providers adopt health IT certified to the 2015 Edition at different times. We support requiring the ability of 2015 Edition health IT to send and receive both Release 1.1 and Release 2.0 until all certified health IT products include C-CDA Release 2.0.

§ 170.315(b)(3)—Electronic Prescribing

We support the proposal to include additional transactions related to electronic prescribing, particularly the Fill Status transaction. Fill Status is critical in understanding whether an individual is "adherent" to a prescribed medication regimen. In addition to its uses in quality measurement and research, this information can shape a more meaningful conversation between an individual and her care team about why she has not filled a prescription, thereby enabling the evolution of a new plan of care that takes into account the individual's quality of life goals and addresses financial or logistical barriers to medications.

§ 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 C-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.[5]

[5] 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.

ONC asks about optional sections to include, and 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 of the survey respondents set or track goals for their health all or most of the time.[6] Looking forward, we encourage ONC to consider opportunities to require certified health IT to include the capability for an individual to review, audit, and verify any care plans included in his or her record.

§ 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. 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 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. Including patients' disability status, functional limitations and SO/GI data will help to identify and address existing health disparities. We understand why this NPRM is silent on how providers must use this capability, but we urge again that complementary policy regulations (namely Meaningful Use) should also require that providers *use* this capability and demonstrate a reduction in disparities in at least one measure.

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[6] 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(d)(4)—Amendments

Amendments are an important form of patient- or person-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 record amendments made by patients 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.

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

We appreciate ONC's proposed clarification that the View/Download/Transmit 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 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.[7]

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 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 this information 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.

ONC also asks whether the "View, Download, and Transmit" criterion should employ Web Content Accessibility Guidelines 2.0 Level A or Level AA. We very much appreciate ONC's efforts to provide better access and viewing of health information for individuals with

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[7] 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.

disabilities by 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.

§ 170.315(f)(4)—Transmission to Cancer Registries

Though we do not offer comment on the related sections, we support the proposed requirements related to transmission to various public health agencies and registries, including syndromic surveillance. In addition to transmission to cancer registries, we encourage ONC to consider expanding this requirement to support transmission to additional types of clinical registries.

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

The C-P Alliance 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.

Thank you again for the opportunity to provide comment on the proposed rule for 2015 Edition of Certified Health Information Technology and the 2015 Edition Base EHR Definition. If you have any questions, please contact either of the Consumer-Purchaser Alliance's co-chairs, Debra L. Ness, President of the National Partnership for Women & Families, or Bill Kramer, Executive Director for National Health Policy at the Pacific Business Group on Health.

Sincerely,

Organizations listed in alphabetical order
American Association on Health and Disability
Center for Patient Partnerships, University of Wisconsin—Madison
Consumers' CHECKBOOK/Center for the Study of Services
The Empowered Patient Coalition

Health Policy Corporation of Iowa
Iowa Health Buyer's Alliance
Lehigh Valley Business Coalition on Healthcare
Memphis Business Group on Health
Minnesota Health Action Group
National Business Coalition on Health
National Health Law Program
National Partnership for Women & Families
Pacific Business Group on Health
PULSE of America
St. Louis Area Business Health Coalition
Wyoming Business Coalition on Health