



February 25, 2011

Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: Joshua Seidman
Mary Switzer Building
330 C Street, SW, Suite 1200
Washington, DC 20201

Submitted electronically at <http://www.regulations.gov>

RE: Meaningful Use Workgroup Request for Comments Regarding Meaningful Use Stage 2

Dear Members of the Health IT Policy Committee,

The undersigned consumer organizations are members of the Consumer Partnership for e-Health (CPeH) and the Campaign for Better Care (CBC). The CPeH is a coalition of consumer, patient, and labor organizations working on both the national and local levels that, since 2005, has advocated for patient-centered policies related to health IT. We are dedicated to changing the way health care is organized, financed, and delivered by using information more effectively. The CBC is a broad-based coalition of more than 150 consumer organizations representing diverse constituencies with a direct stake in improving the health, economic security and quality of life for older adults with multiple health conditions and their families.

We greatly appreciate this opportunity to comment on the Health Information Technology (HIT) Policy Committee Meaningful Use Workgroup's Request for Comments (RFC) regarding Meaningful Use Stage 2. The open, deliberative, and transparent process that was used to develop the Stage 1 meaningful use requirements resulted in a strong, sensible, and patient-centered rule, and we are pleased that a similar process is transpiring for Stages 2 and 3.

Robust advancement of meaningful use criteria is essential both to ensure a return on investment for taxpayers who are funding the incentives and to lay a firm foundation for meeting the broad goals of health care reform. We applaud the numerous critical advancements in the proposed criteria, which, in our view, indicate that Stage 2 Meaningful Use will move us even closer to the information-rich, patient-centered health care system that we all desire. At the same time, we believe there are a number of opportunities to strengthen the criteria in order to maximize the value of health IT to all stakeholders, especially patients and their caregivers.

As we continue deliberation about how best to evolve the meaningful use criteria, we should keep in mind the critical need for systems that will enable patients to have a longitudinal health record that allows for seamless integration of health information, coordination of care across the continuum, and the ability to monitor improvements in outcomes and functional status. Achieving these objectives requires data systems and measurement tools that allow patient-reported data to be captured and accessed across the continuum of care. Patients with multiple chronic conditions – the highest users of health care with the poorest outcomes and the greatest costs – especially stand to experience significant and lasting improvements in their care as a

result of these advancements. Such advancements in information sharing will also help patients and their family caregivers to take more active roles in achieving the improved outcomes we all want

Consumer Views on Health IT

The path forward begins with understanding the roles consumers can play in advancing the goals of health care reform, and then ensuring meaningful use supports those roles. Consumers will play the following roles in using information to transform our health care system:

- 1. Acting as Agents of Change.** Being agents of change with regard to personal care means becoming educated about one's own health issues and any potential treatments or interventions that may be pursued; communicating with care providers about preferences, priorities, and values; asking questions; following through with actions required to meet health goals; and providing feedback about care experiences.
- 2. Making Informed Decisions.** Patients and families need reliable, valid, and meaningful information to make decisions about their care. Participation in a shared decision making process has been shown to improve not only patient experience, but also overall outcomes, often at a lower cost.¹
- 3. Verifying Facts and Providing Context.** Patients and their families possess unique information that is critical for creating a comprehensive picture of their overall health and making an effective plan for addressing their health needs. They provide the context of how clinical facts relate to the bigger picture of their daily lives, which is a vital part of ensuring care plan efficacy. They also play an important role in verifying the accuracy of information held by care team members and can help keep this information updated.
- 4. Integrating Better Health into the Full Context of our Lives.** The degree to which people incorporate health care and self-management into their daily lives will have a tremendous impact on their ability to make and meet health goals. Whether an individual's health goals are primarily related to wellness and prevention or chronic disease management, health IT can help them track, measure, understand, and manage specific health needs. This is particularly important for individuals with multiple chronic conditions and their caregivers.

Stage 1 criteria laid a basic foundation for fulfillment of these roles, upon which Stages 2 and 3 must build. In addition, activities prompted by other investments in information exchange made by the American Recovery and Reinvestment Act of 2009, and the emerging delivery and payment system reform initiatives included in the Affordable Care Act (ACA), also call on patients and their families to interact with the health care system in more effective ways. As deliberations about the meaningful use criteria for Stages 2 and 3 continue, it is critical to take the evolving landscape into consideration.

¹ Kennedy AD, Sculpher MJ, Coulter A, Bwyer N, Rees M, Abrams KR, et al. Effects of decision aids for menorrhagia on treatment choices, health outcomes, and costs. *JAMA*. Year;288(21);2701–8; Stewart M, Brown JB, Donner A, McWhinney IR, Oates J, Weston WW, et al. The impact of patient-centered care on outcomes. *J Fam Practice*. 2000;49(9):796–804; Little P, Everitt H, Williamson I, Warner G, Moore M, Gould C, et al. Observational study of effect of patient centeredness and positive approach on outcomes of general practice consultations. *BMJ*. 2001;323(7318):908–11; Beck R, Daughtridge R, Sloane PD. Physician-patient communication in the primary care office: a systematic review. *J Am Board Fam Pract*. 2002;15(1):25–38.

Health IT and the Environment of Reform

Health Information Exchange

Many health care providers and communities are currently exploring how they can work together and form new partnerships – such as Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes (PCMHs). These new partnerships and alliances call on providers to work together across the continuum of care and will depend on having an effective strategy for sharing, managing, and using information to improve care and reduce costs. The current state of health information exchange is far from ideal, but progress is being made. The recently announced collaborations under The Direct Project² prove that sophisticated and robust data exchange is presently possible in some areas. While this program has its own limitations, it shines a light on possibilities for more widespread exchange of information in the very near future. CMS and the Office of the National Coordinator for HIT (ONC) have an opportunity in Stage 2 meaningful use to build on these advancements to catalyze health information exchange.

Patient and Family Engagement

Patient and family engagement will be essential to the success of new models of care delivery, if they are to meet consumer expectations and if our nation is to meet national health goals being developed as a part of the National Quality Strategy and Plan. A central tenant of the ACA is patient-centered care, which is mentioned 38 times in Title III (“Improving the Quality and Efficiency of Health Care”) alone. Regardless of how communities approach delivery and payment system reform, new care delivery models must provide comprehensive, coordinated, patient-centered care. Since they use technology to help them manage information in every other area of their lives, consumers understand that more effective use of technology can improve the quality of the care they receive and their experiences of care, including their own ability to participate in their care.

Our specific comments and recommendations below are intended to provide direction for ensuring that Stage 2 meaningful use continues to support patients and their families in the roles they will play in creating an information-rich, patient-centered health care system.

Important Strides Forward

We strongly support the transition of all “menu” (optional) criteria from Stage 1 to “core” (required) in Stage 2. Many of these criteria, such as conducting medication reconciliation, providing summary care records, providing patients with timely electronic access to their health information, sending reminders for preventive and follow-up care, recording advance directives, and providing patient-specific educational materials, are foundational for enabling consumers and patients to fulfill their roles in making health and health care better, and should no longer be considered optional.

² See, US Department of Health & Human Services, Office of the National Coordinator for Health IT. (2011, February 2). ONC announces launch of “Direct Project” pilots [Press Release]. Retrieved from <http://www.hhs.gov/news/press/2011pres/01/20110202a.html>

These criteria also have efficiency implications. For example, older adults with multiple chronic conditions are often shuffled between specialists who do not communicate about tests they order, diagnoses they make, or treatments they prescribe. Consequently, large numbers of older adults with multiple chronic conditions report duplicate tests and procedures, conflicting diagnoses, contradictory medical information, and lack of adequate information about potential drug interactions.³ The foundational criteria included in Stage 1 provide information necessary to begin addressing overuse, underuse and misuse of health care resources.

Advancements in key criteria having an impact on the quality, safety and efficiency of care delivery are critical and have our full support. The increased threshold and expansion of the CPOE requirements, increased threshold for the medication reconciliation criterion, and advancement of the ePrescribing threshold will be critical to improving patient safety and minimizing overuse. The dangers of having multiple providers prescribing medications without knowing all the medications a person is taking are very real to consumers, especially as they age. Seventy-six percent of Americans over age 60 use two or more prescription drugs over the course of a month, and *37 percent use five or more*.⁴ Overuse of laboratory and radiology tests results in unnecessary, wasteful spending, and in the case of radiological tests, can also put patients at risk of unnecessary radiation exposure. As new delivery and payment models are tested under the ACA provisions, and providers are held increasingly accountable for both the quality and efficiency of the care they provide, employing the information management capabilities of health IT will be essential.

ONC should explore how to increase the impact of ePrescribing by encouraging the use of automated fill-status messages back to the ordering clinician. In 2010, Harvard Medical School found that over 20 percent of first-time prescriptions went unfilled, with even higher rates for first-time prescriptions for chronic diseases.⁵ While the capability of receiving fill-status exists in current systems, most often this requires a query by the ordering clinician at an additional cost. In a busy clinic or hospital environment, this information should be fed back to the clinician automatically, thus enabling a follow-up discussion between clinicians and their patients about why they did not fill prescribed medications and a shared decision-making process to explore other alternatives.

Revising the clinical decision support (CDS) criterion to require that it be based on evidence and that it focuses on improving performance on high-priority health conditions is a significant improvement over Stage 1. Much of the benefit of health IT in improving quality and safety is achieved through implementation of clinical decision support, making this a critical area for steady advancement. We believe this is a critical opportunity to engage specialists by requesting that each specialty identify evidence-based CDS rules in their area of expertise, then use these as part of a menu from which providers can choose to qualify for meaningful use incentives. A robust threshold needs to be set, such as requiring each provider to select at least three specialty-specific rules to implement by 2013, advancing to implementation of 10 specialty-specific rules by 2015. It is critical to note that monitoring use of

³ Anderson, G. (2007). *Chartbook, Chronic Conditions: Making the Case for Ongoing Care*. Johns Hopkins University. Retrieved October 1, 2009, from http://www.fightchronicdisease.org/news/pfcd/documents/ChronicCareChartbook_FINAL.pdf

⁴ Quiping, G., Dillon, C., & Burt, V. (September 2010). Prescription Drug Use Continues to Increase: U.S. Prescription Drug Data for 2007-2008. NCHS Data Brief, No. 42. Centers for Disease Control and Prevention.

⁵ Fischer MA, Stedman MR, Lii J, et al. (2010). Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions. *J Gen Intern Med.* 25, 284-290.

these technologies should be accompanied by a mechanism for monitoring the safety of these systems.

We are particularly pleased by advancements in the area of advance directives.

Applying this criterion to eligible providers and eligible hospitals and requiring the content, as well as the existence of an advance directive be recorded, greatly increases the impact of this criterion, which is a key opportunity for engaging patients and their families in decision-making about their care. We feel it is vital to lift age restrictions, since advance directives can apply to people who are not age 65 and older, but we recognize the complexity involved in applying this criterion to adolescent populations. The benefit – both to patients and their care teams – of creating opportunities to have these important discussions and providing information that is pivotal to following a patient’s preferences for his or her care cannot be overstated.

We particularly support the additional advancements proposed to criteria that help engage patients and families in their care. These criteria will go a long way toward helping patients and their caregivers fulfill their roles in managing their own care, providing critical information to their providers, and incorporating important health-related actions into the fuller context of their lives. We continue to support the sending of reminders to patients, in accordance with their preferences, and we also continue to support eliminating age restrictions, since people of any age may have chronic illnesses and preventive/wellness needs. More expansive use of patient reminders will also complement the new protections in both the private insurance market and in Medicare that require coverage of preventive services at no cost-sharing to the consumer.

We also strongly support the new criterion of offering online secure patient messaging to patients and their families. The patient/provider relationship is substantially enhanced by improving communication. When used in the context of a care team, this criterion has the potential to improve provider experience, as well. **We encourage ONC to include this new criterion as core in Stage 2, at a threshold of at least 50% of patients who designate their preference for communication as electronic, due to its importance in enabling better communication and coordination between patients and their providers.**

The shift in construct from “copy and access” to “copy and view/download” helps clarify the purposes for which patients need access to their health information, and the progression in criteria ensures that those information needs will be met. More timely receipt of a copy of an individual’s medical record, which is enabled by an electronic environment, is an important element to maintain through the Stage 2 copy criterion. View/download moves us closer to the point of having real-time access to portable information. The additional steps toward this goal– the criteria of requiring that electronic discharge instructions and clinical summaries of office visits be offered – are critical, because they convey the information that patients and their families need, relative to a specific encounter, to participate in the roles discussed above. The proposed elements of discharge summaries and clinical summaries are on target, but we advise ONC to ensure alignment with existing standards, such as The Joint Commission requirements.

Likewise, in order for individuals to better manage their health and health care needs on an ongoing basis, they need longitudinal information that is comprehensive and can help them – in collaboration with their provider – make the decisions that are right for them, ensure that the information in their medical record is correct, and ultimately, integrate actions necessary for meeting health goals into their daily lives. The new criterion for eligible hospitals requiring a

secure portal and the revised criterion for eligible providers requiring access to a longitudinal record ensures that providers receiving incentives for meaningful use are supporting their patients in being fully engaged by providing access to timely, portable, and complete information.

Holding providers accountable for actual usage of the “portal” is entirely appropriate and we strongly urge ONC to resist pressure from the provider community to absolve them from responsibility for making these services available and useful to their patients. Given the current health care environment, where the vast majority of information is not electronic, and where patients are not necessarily aware of (or accustomed to) efforts to make health information available to them in electronic formats, providers have a critical role to play in making sure that these new capabilities are used. Patients still trust their providers more than other information sources, and therefore holding providers accountable for a reasonable threshold of actual usage by their patients is entirely appropriate.

In other industries, performance is routinely based on how well customer needs are met, as indicated by sales or usage of a particular product. Providers have a significant impact on whether or not consumers use the tools provided to them, as has been shown by leaders in consumer engagement efforts. The fact that they do not have 100 percent control over whether a patient uses a “portal” is no justification for backing away from this critical step.

You have already acknowledged the role clinicians play in helping their patients become aware of the availability of electronic information by removing the “upon request” caveat from several of the Stage 1 criteria, an improvement we support heartily. Maintaining provider accountability for actual usage of the information they provide further acknowledges that these criteria are about much more than simply informing patients about the availability of electronic information. They are also about helping patients understand – through communication from their providers – that they are encouraged to use this information and to participate in their own care. This is a significant culture shift. Holding providers accountable for the actual use of these new tools, with reasonable accommodation for patients who either do not have access to or don’t prefer electronic tools, will be much more effective and easier to measure than holding providers accountable for simply having offered this kind of access to their patients. **We would suggest that this threshold be increased to 30% rather than 20%, in order to advance patient engagement more strongly.**

The tentative Stage 3 criteria for engaging patients and their families – the provision of electronic self-management tools, electronic data exchange with PHRs, patient reporting on experience of care measures, and incorporating patient-generated data into EHRs and clinician workflow – are directionally appropriate. We suggest requiring the use of experience of care surveys in Stage 2, with particular emphasis on evaluating concepts related to communication and care coordination included in the PCMH and HIT CAHPS surveys in Stage 2. These surveys are currently in use or are about to be available for use, and many providers are already using one of the CAHPS family of surveys as part of other improvement and reporting efforts. Quality measurement resources should be prioritized to develop a cross-cutting measure based on subsets of questions from these surveys to enable evaluation of patient experience of care as a result of meaningful use of health IT. In Stage 3, the results of these surveys could be fed back to the provider electronically.

For the other tentative Stage 3 criteria (self-management tools, data exchange with PHRs, and incorporating patient-generated data into EHRs and clinician workflow), maintaining or

increasing the requirement of at least 20% of patients using the “portal” is a critical stepping stone for helping providers succeed in Stage 3, and yet another reason we urge you to maintain it. The critical difference that would be advanced in these Stage 3 measures is adding a bi-directional flow of information.

Given that patients are consistently frustrated by the lack of coordination in the health care system, we strongly support the proposed addition of a new criterion requiring providers to record a longitudinal care plan for patients with high-priority health conditions. In order to improve care coordination and outcomes of care, there must be a way for all members of the care team, including the patient and his or her caregivers, to formulate, share, and update a longitudinal plan of care. Stage 2 meaningful use MUST begin addressing the need to track information longitudinally to enable measurement of improvement over time, and to ensure that the care plans reflect patient preferences, shared goals and agreed-upon action steps. This is especially important for individuals with multiple chronic conditions, for whom good health and quality of life depends on taking into account not just clinical needs but also external factors like home environment and patient values and preferences.

While ONC should work on how to define the Stage 2 care plan, with particular emphasis on essential data elements, the new criterion of recording a list of care team members should be considered essential information, and therefore retained in the final recommendations for Stage 2 criteria, with a higher threshold. Other existing Stage 2 criteria that provide essential information for care plans are maintaining an up-to-date problem list, medication list, and medication allergy list, recording advance directive status and content, and recording patient preferences for language and communication. These pieces of information will help comprise a longitudinal, shared care plan in future stages of meaningful use and will have significant implications for enabling full participation by patients and their caregivers as agents of change, informed decision-makers, verifiers of information, and integrators of information and action.

Emphasis on Exchange of Information

ONC has rightly stated from the outset that Stage 2 meaningful use will focus on advancing health information exchange (HIE). While we are pleased that there has been advancement in the area of health information exchange, we do not feel that this advancement is sufficient, given the tremendous benefit that comes with exchange of electronic data and the demands of the delivery and payment reforms our health care system will be testing and instituting in the very near future. Meaningful use incentives must be leveraged to drive the marketplace toward the private and secure sharing of information to enable higher quality, better-coordinated care. The proposed criteria could do more to leverage the progress being made in Stage 1 and the new Stage 2 criteria.

One way to leverage existing criteria to advance HIE is to tie the requirement of providing a summary of care record to the requirement to exchange information electronically. First, any reference to a “test” of HIE should be eliminated. If Stage 2 meaningful use is meant to focus on HIE, then providers receiving incentive money should be well-beyond simply testing their ability to exchange information; they should be actively doing it on a regular basis, at least for a subset of their population. Requiring the provision of the summary of care record in an electronic format for 30% of their patients transitioning to another setting of care would not only be a practical step with real value, but would also assist providers in identifying the “three external providers in a primary referral network,” since they could simply identify the three providers to which they most often discharge patients. Another

way to leverage existing criteria in advancement of HIE is to **specify in the medication reconciliation criterion (which will become core) that the receiving provider perform medication reconciliation using electronic information (presumably that is included in the summary of care record above) from the provider sending the patient**, when a transition occurs.

Advancing the incorporation of lab data into EHRs, is another criterion that is particularly important to advance more rapidly. Today, lab results are not widely incorporated into EHRs, due to standards and interoperability issues, and business reasons resulting from this lack of standards. In addition to moving this criterion from menu to core, we strongly suggest that ONC prioritize the development of standards in this area and task the HIT Standards Committee to oversee this effort. Not only do providers need these data for clinical decision-making, but patients who need specific lab information for purposes of self-management also need to have access to lab results as they gain access to their health information through their provider's "portal." A complementary effort to identify the best ways to interpret and display these results should also be undertaken.

We strongly support the additional requirement that providers must record demographics of 80% of patients and use these demographics to produce stratified quality reports. This criterion could be further strengthened by requiring that providers submit summary-level stratified quality reports to CMS. The internal use of stratified quality reports is fundamental to providers' ability to tackle health care disparities within their practice or hospital. Reporting this information to CMS will both provide a robust way to indicate that a provider is using health IT in this way and establish awareness by the provider of existing disparities of care.

We also urge you to align the required demographic categories and data collection standards with those required under Section 4302 of the ACA and any ensuing regulations or guidance implementing that provision. At a minimum, this means that collection of disability status should be required in addition to race, ethnicity, primary language, and gender (or sex), as well as any additional requirements the Secretary of HHS may recommend. The addition of disability status, and potentially other categories such as sexual orientation and gender identity, is especially important given a recent report on health disparities and inequalities in the U.S. by the Centers for Disease Control and Prevention (CDC) which found a dearth of data on disability status, as well as sexual orientation and identity, and the lack of consistency in data where it exists.⁶ We hope that alignment with implementation of ACA Section 4302 will also mean the implementation of the Institute of Medicine's recommendations for standards and best practices for collecting race, granular ethnicity, and primary language data included in the 2009 report, *Race, Ethnicity and Language Data: Standardization for Health Care Quality Improvement*. Finally, recording preferred language for a higher percentage of patients is an important component of shared longitudinal care plans,.

New Components to Consider

Of the consumer roles we laid out above, perhaps the least developed in the proposed criteria is the role of consumers as sources of verification and contextual information. In the very near future there needs to be a means by which patients can flag and

⁶U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. (2011, January 14). Morbidity and Mortality Weekly Report: *CDC Health Disparities and Inequalities Report – United States, 2011*. Retrieved on 21 January 2011, from <http://www.cdc.gov/mmwr/pdf/other/su6001.pdf>.

correct data in their health record. Any changes by the patient should be identifiable to the provider as such. Incorrect information in a patient’s chart is most often identified by patients and their families, even in a paper-based world where access to information is not widespread. As patients become better able to access their health information, and as more data sources begin contributing to the electronic health record, it is likely that an increasing number of errors will be identified in EHRs. Many providers and industry representatives have voiced concern over this issue. It is critical that we begin using patients and their families as a resource in that effort – a step enabled by the electronic environment itself, and one that has tremendous safety implications. Meaningful use should not be silent on this opportunity to engage patients and their families, and therefore we encourage the Policy Committee to consider an “information reconciliation” criterion.

We also urge you to ensure that Stage 2 Meaningful Use includes the key functions to support Stage 2 Quality Measures. Before drafting a final rule, ONC should analyze how capabilities reflected in Stage 2 Meaningful Use Criteria will support desired quality measures. Based on current deliberations of the Quality Measures Work Group, Stage 2 Meaningful Use – at a minimum – must permit construction of longitudinal measures (such as readmissions) by interfacing with claims and administrative data using common identifiers and enable patient-reported data from an external source to be captured.

This is a critical component of Stage 2 Meaningful Use, and has implications for aligning meaningful use quality measures with the ACA. For instance, Sec. 4103 of the ACA provide for Medicare coverage of a new annual wellness visit that includes a health risk assessment and personalized prevention planning. The Policy Committee should look at tools such as Dartmouth’s “How’s Your Health?” survey tool,⁷ among others, to fill the role of the health risk assessment and explore how the data generated by the tool can be incorporated into meaningful use. For example, some existing tools provide online patient education materials based on answers provided by the patient, and some also ask important questions regarding patient centered outcomes, such as functional status and patient experiences. Providers may be able to achieve a number of criteria in both the first and second policy priorities through one survey tool if we plan strategically now. Incorporation of these kinds of tools will enable movement away from functional criteria in favor of outcomes for meeting meaningful use criteria.

Select RFC Questions

2. For patient/family access to personal health information, what standards should exist regarding accessibility for people with disabilities (e.g., interoperability with assistive technologies to support those with hearing, visual, speech, or mobile impairments)?

There are over 50 million Americans with disabilities in the United States. This includes people with sensory disabilities such as people who have low vision, are blind, and people who are deaf or have speech disabilities. These individuals, as well as those who have other disabilities, will need to have equal access to personal health information using electronic tools – whether for their own personal care, the care of someone for whom they are the primary caregiver, or for purposes of their job as a professional caregiver. Many people with disabilities use common software-based assistive technologies such as screen readers, screen magnifiers, speech

⁷ See,

<http://www.ihl.org/IHI/Topics/Improvement/ImprovementMethods/ImprovementStories/HowsYourHealthSurveyToBringPatientsandPhysiciansontotheSamePage.htm>

synthesizers, and voice input software that operate in conjunction with graphical desktop browsers (among other user agents). Hardware assistive technologies may include alternative keyboards and pointing devices.

There are a number of existing standards and practices which go a long way toward ensuring accessibility and usability by people with disabilities. For example:

- Websites should be designed using the Web Content Accessibility Guidelines (WCAG 2.0) developed by the World Wide Web Consortium;
- Information technology should reflect the federal requirements in Section 508 of the Rehabilitation Act for accessible Electronic and Information Technology (EIT) for accessible equipment;
- Any telephone assistance hotlines – for instance, Interactive Voice Response (IVR) systems – should comport with the requirements for accessibility and usability found in the Communications Act (Sections 255 and 251);
- Telephone call center services representatives, including via click through from websites, should be trained in receiving calls from people with hearing disabilities and from people with speech disabilities who use the various forms of relay service.

The disability community, which may be among those who will benefit the most from health IT innovations, may find itself unable to use these systems if specific requirements for accessibility and usability are not included in meaningful use implementation.

3. What strategies should be used to ensure that barriers to patient access – whether secondary to limited internet access, low health literacy and/or disability – are appropriately addressed?

The primary way for ONC to ensure that barriers to patient access are addressed is to coordinate well with other agencies working on various elements of patient access, such as the Federal Trade Commission regarding broadband issues, and CDC and AHRQ regarding health literacy. One suggestion is for ONC to seek recommendations directly from these agencies.

It is critical to note that there are a number of barriers to patient access, not just the ones listed. For example, people with limited English proficiency will experience significant barriers to access if information is not made available in their language or through the use of bilingual interpreters. ONC should leverage the HHS Limited English Proficiency (LEP) guidance to address this specific barrier.

Determining the most predominant barriers to patient access and use of electronic health information in addition to those listed here will be critically important. Such data may already be available, and if so, should be leveraged in this effort. Holding focus groups with individuals who typically experience these barriers to access in order to determine potential real-world solutions is an important step toward engaging consumers themselves in ways that leverage their status as agents of change.

5. For future stages of meaningful use assessment, should CMS provide an alternative way to achieve meaningful use based on demonstration of high performance on clinical quality measures (e.g., can either satisfy utilization measures for recording allergies, conducting CPOE, drug-drug interaction checking, etc, or demonstrate low rates of adverse drug events)?

We feel that if this issue is addressed appropriately, it would lead to the ultimate goal – specific performance thresholds based on outcomes – in a way that is least burdensome for providers. A benefit of moving toward accountability for outcomes, rather than focusing on technology features and functions, is the elimination of the need for functional criteria to keep up with rapidly changing technology.. Additionally, most new models of care being advanced through the ACA also focus on outcomes, creating opportunity for alignment.

While we could support an alternative method of achieving meaningful use for the reasons mentioned above, we feel that at this point in time, **such a move is premature**. Today’s clinical quality measures are simply not sufficient for supporting meaningful use, because they are often not particularly meaningful to consumers and patients. In addition, robust, patient-centered outcomes measures are not generally available, and since it is possible to achieve good “clinical outcomes” (at least as we define them in today’s provider-centric quality measures) without substantially engaging patients and families, we must ensure that any alternative method of achieving meaningful use reflects high levels of patient engagement and care coordination. One approach that could be explored would be to offer providers an alternative only if they have achieved meaningful use in Stages 1 and 2 and 3 – assuming that Stages 2 and 3 contain strong patient engagement and care coordination criteria.

8. What are the reasonable elements that should make up a care plan, clinical summary, and discharge summary?

We are very pleased with the required elements of clinical summaries and discharge summaries as listed in the request for comment, as they represent key components of the comprehensive information necessary for full understanding about what transpired during an office visit or hospitalization. Advancing the concept of a longitudinal, shared care plan – which is only possible with the use of health information exchange – is a critical step to take in Stage 2 meaningful use. While we understand that instituting the practice of creating, sharing, and providing care according to a shared care plan is a significant change in care delivery that will require some time to achieve, we believe that determining the basic and most critical elements to include in a care plan is a concrete, very achievable step to take in Stage 2. The most critical elements to include in a care plan are:

- List of active diagnoses
- Goals for treatment/care and timeline(s)
- Care team member names* and contact information
- Advance directive status and content*
- Need for and capabilities of caregivers at home
- Assessment of living situation and available resources, relative to need
- Patient preferences for language and communication*
- Necessary actions, responsible party, timeline, and status
- Anticipated transitions and approximate timeline
- Evidence of patient and family participation in developing the plan

Several of these critical elements (indicated by the *) are already included in other Meaningful Use criteria. Requiring collection of the additional elements in Stage 2 Meaningful Use would both advance the concept of a longitudinal, shared care plan in a very concrete way and create tremendous value for patients, their families, and their care teams.

Conclusion

We look forward to continuing to work with you as the Stage 2 requirements are further refined, and additional components, like expanded health information exchange requirements, quality measure reporting requirements, and privacy and security objectives, are incorporated. In particular, we are interested to be part of the discussion about what, if any, Stage 2 criteria will be considered menu rather than core, since we believe the approach being advocated by some to make all new criteria optional is based on flawed reasoning and will not result in the kind of advancement in Stage 2 of meaningful use that was intended by Congress or ONC. We also hope to learn more about your inclinations regarding flexibility for state Medicaid programs and whether or not to update Stage 1 criteria in future rulemaking (so that a provider who first demonstrates meaningful use in 2013 or 2014, for instance, could be subject to updated criteria that take into consideration advancements in EHR technology and health information exchange), as was pondered in the Stage 1 final rule.

Thank you again for this opportunity to weigh in on the early phases of development of the Stage 2 and 3 meaningful use criteria. In addition to our broad comments above, we have included a grid as an appendix that outlines our specific recommendations in a summary fashion. We appreciate the hours of hard work and significant advancements in the proposed criteria and look forward to working with you to make the most of this important opportunity.

Sincerely,

AARP

Advocacy for Patients with Chronic Illness, Inc.

AFL-CIO

American Association on Health and Disability

American Hospice Foundation

Caring from a Distance

Center for Democracy & Technology

Childbirth Connection

Consumers for Affordable Health Care

Consumers Union

Families USA

Family Caregiver Alliance

Healthwise

Mothers Against Medical Error

National Alliance for Caregiving

National Coalition for Cancer Survivorship

National Consumers League

National Family Caregivers Association

National Health Law Program

National Partnership for Women & Families

National Women's Health Network

OWL - The Voice of Midlife and Older Women

SEIU

The Children's Partnership

The Leadership Conference on Civil and Human Rights

Stage 2 Meaningful Use Request for Comment Matrix

Stage 1 Final Rule	Proposed Stage 2	MU Workgroup Comment/Question	CPeH Comments
Improving quality, safety, efficiency, and reducing health disparities			
CPOE for medication orders (30%)	CPOE (by licensed professional) for at least 1 medication, and 1 lab or radiology order for 60% of unique patients who have at least 1 such order (order does not have to be transmitted electronically)		<ul style="list-style-type: none"> Support advancement – both of threshold and to core – and support expansion of requirement
Drug-drug/drug-allergy interaction checks	Employ drug-drug interaction checking and drug allergy checking on appropriate evidence-based interactions	Reporting of drug interaction checks to be defined by quality measures workgroup; seeking to try to avoid “alert-fatigue”	<ul style="list-style-type: none"> Essential information for care plans
E-prescribing (EP) (40%)	60% of orders (outpatient and hospital discharge) transmitted as eRx if fits patient preference	If receiving pharmacy cannot accept eRx, automatically generating electronic fax to pharmacy acceptable	<ul style="list-style-type: none"> Support advancement of threshold Urge ONC to explore how to increase impact by encouraging use of automated fill-status messages back to ordering clinician

Record demographics (50%)	80% of patients have demographics recorded and can use them to produce stratified quality reports		<ul style="list-style-type: none"> • Support advancement of threshold • Recommend requiring that providers submit summary-level stratified quality reports to CMS • Urge alignment of demographic categories and data collection standards with those required under Sec. 4303 of the ACA and any ensuing guidance or regs
Report clinical quality measures electronically	Continue per quality measures workgroup and CMS recommendations	The HIT policy committee quality measures workgroup issued a RFC in December; new measures will be considered after a review of comments	
Maintain problem list (80%)	Problem lists are up-to-date	Expect to drive list to be up-to-date by making it part of patient visit summary and care plans	<ul style="list-style-type: none"> • Essential information for care plans
Maintain active medication list (80%)	Medication lists are up-to-date	Expect to drive list to be up-to-date via medication reconciliation	<ul style="list-style-type: none"> • Essential information for care plans
Maintain medication allergy list (80%)	Medication allergy lists are up-to-date	Expect to drive the list to be up-to-date by making it part of visit summary	<ul style="list-style-type: none"> • Essential information for care plans
Record vital signs (50%)	Continue stage 1		

Record smoking status (50%)	Continue stage 1		
Implement 1 CDS rule	<p>Use CDS to improve performance on high-priority health conditions. Establish CDS attributes for purposes of certification:</p> <ul style="list-style-type: none"> • Authenticated (source cited) • Credible, evidence-based • Patient-context sensitive • Invokes relevant knowledge • Timely • Efficient workflow • Integrated with EHR • Presented to the appropriate party who can take action 		<ul style="list-style-type: none"> • Support expansion and new focus on improving performance on high-priority health conditions • Encourage setting of robust threshold
Implement drug formulary checks	Move to core.	What is the availability of formularies for eligible professionals?	
Record existence of advance directives (EH only) (50%)	For EP and EH: 50% of patients 65 or older have recorded in EHR the result of an advance directive discussion and the directive itself if it exists.	Potential issues include state statutes; challenges in outpatient settings; age; privacy; specialists; needs to be accessible and certifiable; need to define a standard.	<ul style="list-style-type: none"> • Support move to core • Support inclusion of EP • Support increased impact due to improved patient/family engagement • Advocate removal of age description

Incorporate lab results as structured data (40%)	More to core, but only where results are available.		<ul style="list-style-type: none"> Support move to core Recommend ONC prioritize the development of standards in this area and task HIT Standards Committee with oversight
Generate patient lists for specific conditions	Move to core. Generate patient lists for multiple patient-specific parameters.		<ul style="list-style-type: none"> Support move to core
Send patient reminders (20%)	Move to core.	How should an “active patient” be defined?	<ul style="list-style-type: none"> Support move to core Advocate removal of any age restriction
NEW for stage 2	30% of visits have at least one electronic EP note.	Can be scanned, narrative, structured, etc. How to define?	
NEW for stage 2	30% of EH patient days have at least one electronic note by a physician, NP, or PA.	Can be scanned, narrative, structured, etc. How to define?	
NEW for stage 2	30% of EH medication orders are automatically tracked via electronic medication administration recording (EMAR).		
Engage Patients and Families in Their Care			
Provide electronic copy of health information, upon request (50%)	Continue Stage 1.	Only applies to information already stored in the EHR.	<ul style="list-style-type: none"> Support patient access to portable information

<p>Provide electronic copy of discharge instructions (EH) at discharge (50%)</p>	<p>Electronic discharge instructions for hospitals (which are given as the patient is leaving the hospital) are offered to at least 80% of patients (patients may elect to receive only a printed copy of the instructions)</p>	<p>Electronic discharge instructions may include a statement of the patient’s condition, discharge medications, activities and diet, follow-up appointments, pending tests that require follow up, referrals, scheduled tests.</p>	<ul style="list-style-type: none"> • Support advancement of threshold • Support elements of instruction • Support patient access to portable information • Advise ONC alignment with existing standards
<p>EHR-enabled patient-specific educational resources (10%)</p>	<p>Continue Stage 1</p>		<ul style="list-style-type: none"> • Support advancement to core
<p>NEW for Stage 2 (EH)</p>	<p>80% of patients offered the ability to view and download via the EHR’s secure portal or the private and secure service of a business associate within 36 hours of discharge, relevant information contained in the record about hospital inpatient encounter. Data available in both human readable and structured forms. (HIT Standards Committee to define; e.g., use of PDF or text.)</p>	<p>Inpatient summaries include: hospitalization admit and discharge date and location; reason for hospitalization; providers; problem list; medication lists, medication allergies; procedures; immunizations; vital signs at discharge; diagnostic test results (when available); discharge instructions; care transitions summary and plan; discharge summary (when available); gender, race, date of birth, preferred language, advance directives; smoking status. <u>Invite comments on the above.</u></p>	<ul style="list-style-type: none"> • Support shift in construct to “view and download” • Support patient access to longitudinal information

<p>Provide clinical summaries for each office visit (EP) (50%)</p>	<p>Patients have the ability to view and download relevant information about a clinical encounter within 24 hours of the encounter. Follow-up tests that are linked to encounter orders but not ready during the encounter should be included in future summaries of that encounter, within 4 days of becoming available. Data are available in human-readable and structured forms. (HIT Standards Committee to define; e.g., use of PDF or text.)</p>	<p>The following encounter data are included (where relevant): encounter date and location; reasons for encounter; provider; problem list; medication list; medication allergies; procedures; immunizations; vital signs; diagnostic test results; clinical instructions; orders: future appointment requests, referrals, scheduled tests; gender, race, ethnicity, date of birth; preferred language; advance directives; smoking status. <u>Invite comments on the above.</u></p>	<ul style="list-style-type: none"> • Support shift in construct to “view and download” • Support advancement to core • Support for physician accountability for patient use of a “portal” • Advocate rise in threshold to 30% to advance patient engagement
<p>Provide timely electronic access (EP) (10%)</p>	<p>Patients have the ability to view and download (on demand) relevant information contained in the longitudinal record, which has been updated within 4 days of the information being available to the practice. Patient should be able to filter or organize information by date, encounter,</p>	<p>The following data elements are included: encounter dates and locations; reasons for encounters; providers; problem list; medication list; medication allergies; procedures; immunizations; vital signs;</p>	<ul style="list-style-type: none"> • Support shift in construct to “view and download” • Support advancement to core • Support patient access to longitudinal information • Support for physician accountability for patient use of a “portal” • Advocate rise in threshold to

	etc. Data are available in human-readable and structured forms. (HIT Standards Committee to define; e.g., use of PDF or text.)	diagnostic test results; clinical instructions; orders; longitudinal care plan; gender, race, ethnicity, date of birth; preferred language; advance directives; smoking status. <u>Invite comments on the above.</u>	30% to advance patient engagement
This objective sets the measures for “Provide timely electronic access (EP)” and for “Provide clinical summaries for each office visit (EP).”	EPs: 20% of patients use the EHR’s secure portal or the private and secure services of a business associate (that treats patient information confidentially and in accordance with HIPAA business associate expectations), to access their information (for an encounter or for the longitudinal record) at least once. Exclusions: patients without ability to access Internet.		
NEW for Stage 2	(EP only) Online secure messaging is in use.		<ul style="list-style-type: none"> • Strong addition, noting that patient/provider relationship is substantially enhanced by improving communication • Has potential to improve provider experience as well

			<p>when used in context of care team</p> <ul style="list-style-type: none"> • Recommend threshold of at least 50% of patients who designate their preference for communication as electronic
NEW for Stage 2	Patient preferences for communication medium recorded for 10% of patients	How should “communication medium” be defined?	<ul style="list-style-type: none"> • Essential information for care plan
NEW for Stage 2	See MU Workgroup Comment	<p><u>We are seeking comment on what steps will be needed in stage 2 to achieve this proposed stage 3 objective.</u></p> <p>Stage 3: Offer electronic self-management tools to patients with high priority health conditions.</p>	<ul style="list-style-type: none"> • Directionally appropriate and vital to include. Patient use of “portal” is crucial stepping-stone – critical Stage 3 advancement is requirement of bidirectional exchange • Advocate requiring use of experience of care surveys in Stage 2
NEW for Stage 2	See MU Workgroup Comment	<p><u>We are seeking comment on what steps will be needed in stage 2 to achieve this proposed stage 3 objective.</u></p>	<ul style="list-style-type: none"> • Directionally appropriate and vital to include. Patient use of “portal” is crucial stepping-stone – critical Stage 3 advancement is requirement of bidirectional exchange

		Stage 3: EHRs have capability to exchange data with PHRs using standards-based health data exchange.	<ul style="list-style-type: none"> • Advocate requiring use of experience of care surveys in Stage 2
NEW for Stage 2	See MU Workgroup Comment	<p><u>We are seeking comment on what steps will be needed in stage 2 to achieve this proposed stage 3 objective.</u></p> <p>Stage 3: Patients offered capability to report experience of care measures online.</p>	<ul style="list-style-type: none"> • Advocate requiring use of experience of care surveys in Stage 2
NEW for Stage 2	See MU Workgroup Comment	<p><u>We are seeking comment on what steps will be needed in stage 2 to achieve this proposed stage 3 objective.</u></p> <p>Stage 3: Offer capability to upload and incorporate patient-generated data into EHRs and clinician workflow.</p>	<ul style="list-style-type: none"> • Directionally appropriate and vital to include. Patient use of “portal” is crucial stepping-stone – critical Stage 3 advancement is requirement of bidirectional exchange • Recommend requiring use of experience of care surveys in Stage 2
Improve Care Coordination			
Perform test of HIE	Connect to at least three external providers in “primary referral network” or establish	Successful HIE will require development and use of infrastructure like entity-	<ul style="list-style-type: none"> • Support for advancement, but advocate for higher threshold • Proposed advancement is

	an ongoing bidirectional connection with at least one HIE.	level provider directories (ELPDs).	<p>insufficient</p> <ul style="list-style-type: none"> • Recommend tying requirement of providing summary of care record to requirement to exchange information • Consider linking to medication reconciliation by specifying that, in care transitions, the receiving provider perform medication reconciliation using electronic information from provider sending patient • Eliminate any reference to “test”
Perform medication reconciliation (50%)	Medication reconciliation conducted at 80% of care transitions by receiving provider.		<ul style="list-style-type: none"> • Support advancement – both of threshold and core
Provide summary of care record (50%)	Move to core		<ul style="list-style-type: none"> • Support advancement to core • Recommend requiring the provision of record in an electronic format for 30% of patients transitioning to another care setting
NEW for Stage 2	List of care team members (including PCP) available for patients in EHR.		<ul style="list-style-type: none"> • Consider this essential information and advocate for higher threshold • Critical element for care plans

NEW for Stage 2	Record a longitudinal care plan for 20% of patients with high-priority health conditions.	What elements should be included in a longitudinal care plan, including care team members, diagnoses, medications, allergies, goals of care, and other elements?	<ul style="list-style-type: none"> • Strong support for this new criteria • Advocate that the elements put forth by ONC should be mandatory inclusions
Improve Population and Public Health			
Submit immunization data	EH and EP – Mandatory test. Some immunizations are submitted on an ongoing basis to Immunization Information System (IIS), if accepted and required by law.	Stage 2 implies at least some data is submitted to IIS. EH and EP may choose not, for example, to send data through IIS to different states in Stage 2. The goal is to eventually review IIS-generated recommendations.	
Submit reportable lab data	EH – Move to Core. EP – Lab reporting menu. For EPs, ensure that reportable lab results and conditions are submitted to public health agencies either directly or through their performing labs, if accepted and required by law.		
Submit syndromic surveillance data	Move to core through their performing labs, if accepted and required by law.		
NEW for Stage 2	See MU Workgroup Comment	<u>We are seeking comment on what steps will be</u>	

		<p><u>needed in stage 2 to achieve this proposed stage 3 objective.</u></p> <p>Stage 3: Public Health Button for EH and EP. Mandatory test and submit if accepted. Submit notifiable conditions using a reportable public-health submission button. EHR can receive and present public health alerts or follow up requests.</p>	
NEW for Stage 2	See MU Workgroup Comment	<p><u>We are seeking comment on what steps will be needed in stage 2 to achieve this proposed stage 3 objective.</u></p> <p>Stage 3: Patient-generated data submitted to public health agencies.</p>	