May 7, 2012

Submitted Electronically

Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2 Notice of Proposed Rulemaking (CMS-0044-P)

Dear Ms. Tavenner:

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 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 Stage 2 Meaningful Use proposed rule.

From the consumer perspective, health IT can be a critical enabler of safer, more effective and more reliable care, as well as greater consumer engagement in health – and, ultimately, more positive patient experiences and better health outcomes. The proposed rule specifying criteria for Stage 2 of the EHR Incentive Program makes significant advancements in the potential impact of the EHR Incentive program on individual and population-level health and health outcomes. Indeed, meeting the goals of the National Quality Strategy (NQS) is only possible in a health care system that is adequately supported by the meaningful use of health information technology. The HITECH Act – and, in particular, the EHR Incentive Program – is the primary vehicle for creating this capacity. To determine whether and to what extent the proposed rule for Stage 2 of the EHR Incentive Program effectively supports the NQS, we believe it must be assessed against the following goals.

1. Supporting partnership between patients, their family caregivers and their care team;
2. Improving the coordination of care;
3. Increasing health equity; and

4. Enabling new payment and delivery models.

Introduction

When Congress passed the HITECH Act, it clearly intended to establish a foundational infrastructure for health IT to support future reforms to our health care system, not a mere electronic version of the paper charts used today. While advancing technical capabilities within provider settings is vitally important, **the benefits of the EHR Incentive program to broader health reform lie squarely in the areas in which there has been, to date, the least amount of progress. Focusing advancements in Stage 2 Meaningful Use incentive criteria on connecting the silos of our current health care system is <u>essential</u> to improving health outcomes, increasing the health of the population and reducing health care costs.** The goals above provide a "yardstick" for measuring potential impact of Meaningful Use on the overall effort to reform our health care system.

The inability of the U.S. health care system to consistently and effectively deliver coordinated, high quality care takes a tremendous toll on patients and their families. They often must navigate a system where no one is accountable to them, communication breaks down or intentionally excludes them, and, by default, they become the sole integrators of information related to their care. Health IT has a role to play in improving their experiences in all of these areas.

Additionally, improving the health of underserved and vulnerable populations requires health care providers, EHR vendors, and other stakeholders across the health care system to take into consideration the unique needs of these individuals and how technology can make health care and health information more accessible and meaningful to them. Improving health equity also requires collection and use of data to identify differences in provider performance and to target solutions that reduce disparities. Improving the quality and cost of care will require new ways to measure and reward provider performance – ways that are impossible without well-designed and effectively implemented health IT.

The National Partnership for Women & Families (NPWF) conducted a survey during the summer of 2011 evaluating consumer perceptions of value and trust in electronic health record systems. The results of that survey indicate that health care consumers are not only ready for these changes, but they want them.
- Patients see value in EHRs. Nearly 97% of respondents felt EHRs would be useful in improving major aspects of the health care process.
- Hispanic respondents were more likely than the total EHR respondent pool to see EHRs as helping them maintain a healthy lifestyle, saying the EHR helped them understand their conditions and saying that having electronic access to their health information improved their desire to do something to improve their health.

- There is a relationship between the trust patients have in EHRs and the value and usefulness consumers experience.[1]

These results clearly show that consumers see value in EHRs, even if they don't fully understand at this point in time what that value might be. The data also indicate that actually seeing their own health information is a watershed moment for delivering value and trust in these systems.

The proposed rule specifying criteria for Stage 2 of the EHR Incentive Program makes significant advancements that are consistent with the National Partnership's survey research and the most pressing needs for supporting patients and providers in achieving better health outcomes. At the same time, more can and must be done to ensure that patients and families see concrete benefits from the EHR Incentive Program. Below are our comments on the criteria that are most relevant to the priorities identified above, with our suggestions for how they could be strengthened. **We respectfully remind CMS that the intent of the one year delay in Stage 2 is to allow for a robust set of advancements, and therefore we do not agree with the proposal some have advocated to shorten the reporting period to only ninety days**.

Priority 1: Supporting Partnership Between Patients, Their Family Caregivers and Their Care Team

A. View, Download, and Transmit Health Information

Giving patients the ability to view, download, and transmit their own health information AND holding providers accountable for ensuring that at least a small percentage of their active patients take advantage of this critical capability are among the most important criteria in the entire proposed rule.[2]

Patients want to use information in partnership with their providers, and patients who have questions will seek answers. Providers remain one of the most trusted sources of information, and play a vital role in helping their patients understand what information is now easily accessible to them and how they can use it. Holding providers accountable for at least a small percentage of their patients accessing their health information achieves several changes long advocated by providers, and that are essential for success in Stage 3 Meaningful Use (which will focus on outcomes) and the overall transformation of our health care system. Provider accountability for helping their patients to use their new access to information:
- Conveys an expectation from their provider that patients become active participants in, rather than passive recipients of care;
- Fosters a change in clinical culture from paternalism to partnership;
- Increases patients' and caregivers' understanding of their health;

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[11] "Making IT Meaningful: How Consumers Value and Trust Health IT," accessed online at www.nationalpartnership.org/hit.
[2] 77 Fed. Reg. at 13718.

- Significantly and positively impacts the value they experience from electronic health information systems, (which, in turn, supports the HITECH mandate for an educational campaign to improve consumer trust); and
- By building in patients' experience and feedback, improves the design and use of health information technology to meet patients' needs.

It is concerning that some providers argue that they should not be held accountable for patient actions with regard to view, download and transmit when they <u>freely acknowledge their role in helping their patients understand their health information and its implications</u>, even to the point of insisting it be withheld until they can review it themselves. Absolving providers of any responsibility to help patients understand how to access and use that information in partnership with them is merely reinforcing the historically paternalistic approach to health care and does not support patient engagement.

In the NPWF survey, **80% of patients with online access use it. Almost half use it 3 or more times per year, and 25 percent use it 7 or more times per year.** Given this kind of use in 2011, provider ability in 2014 to attain a patient log-in threshold of only 10 percent of their patients seen during the reporting period would seem to be quite achievable.

The findings of NPWF's survey not only support the validity of holding the patient's provider accountable for at least a small percentage of use, but also provide guidance about possible strategies for achieving the criterion. The 80 percent of those who use their online access tend to*:*
- Personally find and correct errors or incomplete information in their medical record;
- Understand their health condition better;
- Keep up with their medications;
- Say they trust their doctor and staff to protect their patient rights; and
- Say they feel well informed by their doctors and staff about privacy issues.

The key determinants in patient use of online information are value and trust, and providers clearly have an influence in these areas. Therefore, we strongly support the new model of view, download and transmit, the 2-measure requirement for meeting the criterion, holding providers accountable for at least a small percentage of use, and the addition of the requirement for eligible hospitals. <u>We would note, however, that whether a patient chooses to view, download, or transmit their health information (or any combination of those 3 actions), should be entirely up to the patient, according to their preference, not the provider's discretion</u>.

We take issue with the proposed timeframes for when the patient's information must become available to the patient, because the proposed approach is not consistent with the **patient's workflow** during transitions of care, and does not ensure information availability to patients and their caregivers when they need it most and are most motivated to follow through with self-care instructions: immediately following an encounter or admission. <u>We urge CMS to require this information to be available within 24 hours of an office visit or discharge from an eligible hospital</u>. The shorter timeframe will also help address cost issues, considering the impact

patient non-adherence has on readmission and the penalties hospitals will incur for avoidable re-hospitalizations starting in October 2012. We urge CMS to provide guidance to hospitals, directing them to consider the information needs of the specific populations they serve as they plan implementation of this criterion. Since <u>patients' caregivers, who play a significant role in preventing unnecessary readmissions, have a tremendous need for information about their loved one's care</u>, it is vital that they be included in strategies used by EPs and EHs to meet this criterion.

B. *Secure Messaging*

Secure Messaging is also among the criteria that have the most positive impact on supporting the active engagement of patients and their caregivers. [3]

When used in concert with the view, download and transmit criterion, the secure messaging requirement not only addresses one of the most consistent complaints among consumers about their health care, but it also acts as a signal to patients that they are encouraged to take a more active role in their health care <u>and that their providers and care team are willing to support them in that role.</u> The lack of more advanced electronic communication methods creates unnecessary barriers to patient engagement.

Secure messaging is a critical step toward advancing access, care coordination and information exchange with the patient and their caregivers as active members of the care team. It also can be used as a strategy for providers to meet the 10% view/download/transmit measure, in that a provider could use secure messaging prior to an appointment to ask if the information they have is up to date and to encourage the patient to view information in their record as part of their preparations for an upcoming visit.   Patients could then very easily respond with updated information, questions they have, or other topics they would like to discuss during their visit. This is a particularly critical feature for long-distance caregivers, whose communication difficulties are compounded by geographical challenges.

It is critical, however, to ensure that communication with patients and their caregivers is accomplished according to their preferences, since not every individual is comfortable with electronic communication. Additionally, individuals may prefer one method of communication for some things, and another for others. We therefore <u>recommend that CMS specifically require collection of patient preferences for communication and that ONC instruct the Health IT Standards Committee (HITSC) to ensure availability of standards for multiple modes of communication for multiple types of information</u>.

For example, the most important message types include:
- Consult/Triage
- Reminder
- Results

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[3] 77 Fed. Reg. at 13728.

- Observations
- Care plan updates
- Ask/answer question – clinical care
- Ask/answer question – billing/finance
- Monitoring/follow-up
- Instructions/feedback/patient education

The most important message formats include:
- US mail
- Secure Email : Direct or equivalent
- Patient portal
- Fax
- Text
- Phone
- Video

We support the secure messaging criterion and measures as proposed, but also see value in making the provider the locus of this criterion, if necessary, but only if there is a timeliness measure included as part of a shift toward provider locus. If CMS opts to take this approach, the threshold should be increased to reflect this change. We feel requiring EPs to send patient-specific secure messages to 30 percent of their active patients and to respond to any messages received within two business days is a reasonable approach.

Concerns about Behavioral Health

CMS is seeking comment on specific concerns about secure messaging with regard to behavioral health. In consultation with our members working in behavioral health, we believe that as long as providers use secure messaging methods, there are no specific concerns with regard to behavioral health from the consumer perspective. Rather, secure messaging can add tremendous value to efforts to improve the coordination of care between behavioral and physical health, something consumers with behavioral health concerns want very much. This particular method of advancing coordination is especially appealing, because it provides an element of control to the patient, who can communicate with the specific providers he or she feels need to know about the behavioral health issues. A behavioral health exemption is therefore counterproductive, and we do not support CMS including such an exemption in the final rule.

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C. *Advance Directives*

According to data gathered by CMS and the Regional Extension Centers, the criterion to record advance directives has been among the most popular menu items of Stage 1, indicating that advancement in Stage 2 is entirely appropriate.[4] While it may be premature to require the recording of the content of advance directives, there is no reason not to make the existing

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[4] 77 Fed. Reg. at 13706.

criterion core for hospitals and menu for eligible providers in Stage 2, and to include a menu option for supplementing presence/absence information with information about WHERE the content of an individual's advance directive is stored. This is a critical opportunity for patient engagement and ensuring that they receive the care they need – and none of the care they don't want. This criterion, as a means of recording what perhaps are the most critical of patient preferences, is central to patient-centered care. Failure to advance this criterion is unacceptable.

With regard to CMS' reasoning for not advancing this criterion due to concerns about state laws, we urge ONC and CMS, as they seek information about these issues for Stage 3 recommendations, to consider the possibilities for incorporating state-specific forms in EHR vendor products. We also encourage them to explore the option of using the Physicians Order for Life Sustaining Treatment (POLST) in Stage 3 as a means of capturing advance-directive information. POLST contains information about an individual's end of life decisions, as well as information about the individual's choices for medical treatment issues, such as tube feedings and the use of antibiotics. The form is structured as a physician's order that is signed by both the physician and the individual, making this a potentially effective means of integrating this type of information in formats already standardized and familiar to EHR users. Another option to pursue in Stage 3 is the development of an advance directive registry, which providers could access as needed, if the EHR flags them by indicating that the individual has executed an advance directive.

D. Additional Criteria

Several other criteria support the goal of patient/provider partnership, and we enthusiastically support the advancements of these criteria that CMS has built into the proposed rule.

Advancing <u>e-prescribing</u>[5], <u>patient reminders</u>[6] and introduction of the <u>family history</u>[7] criteria are all essential components of supporting the patient/provider partnership we envision, and we strongly support the advancements as proposed in the NPRM in each of these areas.

<u>Priority 2: Improving Coordination of Care</u>

Supporting care coordination will require a number of technical functions to facilitate the "people process" that it is. These functions include: improved patient and family access to the health care system and their care team; patient access to and contribution of information in real time; care team member access to and contribution of information in real time; tools to enable communication and the use of information (clinical, personal, psycho-social and environmental); secure, widespread information exchange; monitoring, follow-up and reconciliation of information; identification of and linkage to community supports outside of the health care

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[5] 77 Fed. Reg. at 13703.
[6] 77 Fed. Reg. at 13787.
[7] 77 Fed. Reg. at 13727.

system; and reliable, valid and comprehensive measurement of quality and value, driven by the process of care (individual and population based).

Because care coordination remains challenging in today's fee-for-service payment system, the use of health IT to enable it is unlikely to fit into current workflows, and thus in many cases will require the development of new ones. As noted in the necessary functionalities, <u>care coordination is a team sport</u>, and therefore holding providers accountable for care coordination, by necessity, will mean measuring and reporting processes and outcomes over which an individual provider shares responsibility. This concept is foundational to new payment and delivery system models, such as Accountable Care Organizations and the Medical Home. The proposed rule makes some very positive changes that will support the coordination of care, and <u>we urge CMS and ONC to prioritize requiring the use of the technical capabilities and measurement strategies that meaningfully reflect them</u>.

A. Health Information Exchange

We support eliminating the requirement for a "test of exchange" from Stage 1 (beginning in 2013) and replacing it with at least one case of actual electronic transmission of a care summary for a real patient to another provider of care at a transition or referral, or to a patient-authorized entity (e.g. RHIO).

Central to the goal of better-coordinated care is the ability to share information electronically. The Stage 1 requirement to test exchange was not a meaningful criterion, given that it was not required to be successful, nor did it necessarily require that real patient information be exchanged in the real world. We therefore support the elimination of the requirement of a test of exchange in Stage 1 (starting in 2013),[8] and strongly urge CMS to replace it with something of greater value for encouraging exchange of data.

It is unacceptable, in our view, to allow providers attesting to Stage 1 to receive taxpayer money without taking any steps toward actually exchanging information with other providers. Not only does this reward providers for doing nothing that advances a major benefit of health IT, but it does so in the context of an environment in which electronic exchange of health information is a critical part of many new models of care under the Affordable Care Act (ACA), which will most likely support more widespread health information exchange.

Advancing health information exchange through a "use case" model in Stage 2 will yield greater value for both patients and providers alike than would a separate exchange criterion. In order for this approach to be effective, however, the functional criteria being used as the "use cases" for exchange must include thresholds that are high enough to encourage ongoing electronic sharing of data between and among providers and patients.

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[8] 77 Fed. Reg. at 13704.

While the proposed rule clearly makes an effort in Meaningful Use to increase the electronic exchange of information, there are additional ways of advancing electronic exchange of information through existing criteria that should be incorporated into Stage 2.

Avenues for advancing the electronic exchange of information include:

B. *Summary of Care Record and Care Plan*

The summary of care record is a logical "use case" for demonstrating electronic exchange of information, and we heartily support this direction. We also agree with the <u>intent</u> of CMS' requirement that 10 percent of summaries of care be provided to recipients with no organizational affiliation and using a different vendor, as a way to spread exchange beyond the current silos and barriers to exchange. Requiring exchange to occur with providers using different vendors may be difficult to implement and have unintended consequences (e.g. driving referral patterns artificially in order to meet the incentive requirements, rather than according to patient needs and preferences, as well as provider judgment). Additionally, the specific requirements of the proposed rule would only result in 10 percent of transitions of care or referrals being subject to the requirement to exchange information electronically.

Given the new use case model, the importance of health information exchange to broader health reform efforts, the fact that these requirements will not go into effect until 2014 and will be in effect into perpetuity, <u>10 percent of transitions and referrals is an extremely low bar for electronic information exchange</u>. Stage 2 is intended to significantly advance electronic exchange. This criterion is the primary means of advancing the electronic exchange of information, and <u>therefore we believe that at least 65 percent of all transitions or referrals should include the sharing of a summary of care record, 50% of which will be shared electronically</u>.

To achieve the intent of overcoming silos of information, <u>we encourage CMS to clarify that if eligible providers have difficulty meeting the 50 percent threshold, they could use Direct to exchange information with non-MU eligible entities, such as long-term care providers, home health workers or other community-based supports (such as in-home care providers covered by Medicaid Waivers for home-based care alternatives).</u> Lack of interoperability could also be addressed by banning from certification any vendor products that "block" connectivity as part of their business model. We note that we would support an exception for providers who do not have adequate broadband access (in which case paper care summaries would be required).

Overcoming silos of information will require extensive work to ensure that information is presented in the most organized, meaningful way. The concept of a care plan is a critical notion to advance, and therefore <u>we support including the care plan and care team member list as required elements of a summary of care record</u>. <u>CMS should also stipulate that team members include family caregivers.</u> In many cases, family caregivers are the main providers of care. In

carrying this out, CMS can leverage the Care Transitions Program's standardized approach to defining the type and intensity of the roles family caregivers play (called "DECAF").[9]

CMS should also consider including in the summary of care record an indication of functional status with regard to activities of daily living. This is a key indicator of the specific care needs a patient has. <u>Additionally, two crucial elements are missing from the required content of the care plan: responsible party and timeline.</u> Without these pieces of information, care team members will not know who is responsible for what actions and when they are to be performed in order to reach the stated goals – information that is essential for an actionable plan.

C. Incorporating lab results into EHRs

This criterion is a vital component of enabling more effective care coordination. Not only does it ensure that this critical information is captured electronically as structured data, but doing so then makes this information available to patients through the online access criterion. Lab data is an essential component of monitoring a patient's status and progress for many chronic diseases, and therefore having ready access to lab results is central to coordination of care and patient self-management. <u>We strongly support retaining the proposed criterion as-is in the final rule. Additionally, we support the original HIT Policy Committee's recommendation to require hospitals to send structured labs to EPs.</u> This would help EPs to achieve their structured lab results objective, provide important data for quality metrics, and require the designation of a standard for transport, which benefits hospitals themselves.

D. Maximizing the impact of all criteria

Connecting the Summary of Care Record and Medication Reconciliation

CMS has rightly focused responsibility for medication reconciliation on providers receiving a transfer or referral. This compliments the responsibility placed on the sending/referring provider for electronic transmission of the summary of care.[10] <u>Including the prescriber name and date prescribed for each medication in the medication list would add significant value to the summary of care record for purposes of supporting medication reconciliation</u>, and would be consistent with the need stated above to be clear about who is responsible for what actions. <u>Higher thresholds</u> for both of these criteria are critical, as they could result in the need for EPs and EHs to begin exchanging information with providers that are not eligible for EHR incentives, such as nursing homes and home health, in order to achieve the required threshold. This approach creates alignment with other federal programs being implemented as part of the ACA, such as penalties for unnecessary readmissions and the development of Accountable Care Organizations.

Leveraging the "Generation of Lists by Condition" Criterion

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[9] http://www.caretransitions.org/decaf.asp
[10] 77 Fed. Reg. at 13711.

Providers should have flexibility in generating lists that are most relevant to the populations they serve and their practice. However, we urge CMS to provide enough specificity to ensure that the standards and functionalities necessary for high-value purposes are available to providers in Stage 2. Systems should be equipped to identify and generate reports on patients with multiple chronic conditions, not simply reports by individual condition alone. For example, providers should be able to identify which of their patients have certain co-morbidities, such as diabetes and hypertension, or depression and back pain. Additionally, providers should be required to stratify these reports by disparity variables.

E. Critical missing components of effective care coordination

Care coordination cannot be achieved with only physicians and hospitals exchanging data. Many patients, especially those with multiple chronic conditions, rely on additional care providers for their care and frequently transition from one setting to another. Skilled nursing facilities and home health agencies provide critical transitional care for many individuals between acute care and home, yet they do not receive incentives as part of the EHR Incentive program. Achieving coordinated care will require seamless integration of information systems being implemented by those eligible for EHR incentives and those being implemented by providers that are not eligible for incentives. <u>We urge CMS and ONC to encourage exchange between these silos whenever possible in Stage 2.</u>

There is evidence that nursing homes and home health agencies are far ahead of physician practices in the adoption of health IT[11,12]The penalties to be levied against hospitals for unnecessary readmissions beginning in October of this year provide not only a strong motivator, but also a critical point of alignment between federal programs. <u>Regional Extension Centers and the National Resource Center which supports them should focus significant effort in helping the providers with whom they are working to understand these connections and redesign work flow in ways that bridge the traditional silos of care.</u>

Aggressive pursuit of these capabilities must be part of Stage 3 deliberations, but opportunities remain to move providers and industry leaders in a positive direction through Stage 2. **As set forth above, CMS can note specific criteria which can (and should, whenever possible) be met by sharing information with providers who are not eligible for Meaningful Use incentives.**

Much care, in the form of self-management, occurs in the home. Therefore it is critical to begin building communication loops between patients and their care teams, so that reinforcement of

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[11] Use of Health Information Technology in Home Health and Hospice Agencies: United States 2007 (Resnick and Alwan, 2010); accessed at http://jamia.bmj.com/content/17/4/389.short?q=w_jamia_current_tab.
[12] Use of Electronic Information Systems in Nursing Homes: United States 2004 (Resnick, et. al, 2008); accessed at (http://jamia.bmj.com/content/16/2/179.abstract.

self-care and adjustments to the care plan can be made based on the patient and caregiver's experiences and needs in the home. Integration of patient generated data into the shared medical record will be vital to evolving care coordination efforts, and <u>we urge CMS to begin taking steps toward this goal in Stage 2.</u>

Advancing the ability of electronic systems to record and integrate information gleaned from patients and their family members is essential for their engagement and for better coordination of care. Several proposed Stage 2 criteria represent opportunities to begin accepting patient-generated data, including smoking status, advance directive status, family health history, and medication reconciliation (recording of what the patient is actually taking at home). <u>We urge ONC and CMS to work with the HITSC to prioritize the necessary standards for allowing the incorporation of patient-generated data directly by patients into their medical record.</u>

Priority 3: Increasing Health Equity

Health conditions and their treatment have been shown to vary widely across a number of different demographics, not just race, ethnicity, language and sex. Increasing health equity will require linguistic and cultural competence, and using health IT to collect and apply these relevant demographics is critical for decreasing ALL disparities, improving the health of populations and reducing costs.

Demographic data collection

A. We strongly support increasing the threshold for collecting demographic data from 50 percent to 80 percent in Stage 2. [13]

Disparities in care can only be addressed if data are available to determine where they exist and potential strategies for eliminating them. Reliable and valid calculations of quality metrics can be difficult, however, due to methodological issues related to the small numbers inherent in measuring characteristics of minority populations. Therefore increasing the percentage of patients for whom key demographic data are collected is critically important. We strongly support the requirement in the proposed rule to collect demographic data from 80 percent of patients and encourage CMS to maintain this in the final rule.

In addition, we support the specification that the numerator represents "the number of patients in the denominator who have *all* the elements of demographics (or a specific notation if the patient declined to provide one or more elements or if recording an element is contrary to state law) recorded as structured data" (emphasis added). It is imperative that the requirement not be limited to only one demographic data element, but that all elements be recorded (unless declined by the patient/member).

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[13] 77 Fed. Reg. at 13712.

B. Standards for collecting demographic information must be granular enough to identify differences between sub-populations and aligned across government programs.

The Office of Management and Budget (OMB) standards[14] are not sufficient for purposes of using health IT to decrease disparities in race and ethnicity, and we are very disappointed that CMS has continued to require only the OMB standards for race/ethnicity data collection. For culturally and linguistically diverse groups, such as Asian American subgroups, Native Hawaiians, and Pacific Islanders, and American Indians/Alaskan Natives, data collected using these standards have often been inadequate to identify salient health issues and inform appropriate policy or other interventions. Furthermore, we are concerned that using any standards less robust than the newly-adopted HHS/Office of Minority Health survey standards would undermine HHS's effort to improve the quality and effectiveness of demographic data collection in federal health programs and activities, as called for by § 4302 of the Affordable Care Act (ACA).

Ideally, meaningful use should move toward implementation of the Institute of Medicine's (IOM) 2009 recommendations for the standardized collection of more granular race/ethnicity data. If this is not possible in Stage 2, CMS should use the HHS/OMH survey standards for race/ethnicity, leveraging the existing CDC technical standards to code these data – and plan now for incorporation in Stage 3.

With regard to preferred language, CMS and ONC should adopt the variables recommended in the 2009 IOM Report on Race, Ethnicity and Language Data. In this report, the IOM distinguishes between written and spoken language and advances standards for each. We urge CMS to consider requiring collection of information about both written and spoken language, in light of the new access patients are gaining to individualized health information.

C. Additional demographic data is necessary to support population health and elimination of disparities.

Disparities exist among a number of different demographics, not just race, ethnicity, language and sex. Health IT has a role to play in decreasing ALL disparities and improving health care, a critical component of improving the health of populations and reducing costs.

Disability Status

The ACA mandates the collection of data on "disability status for applicants, recipients, or participants" by "any federally conducted or supported health care or public health program, activity or survey" under § 4302. The six disability status questions contained in the American Community Survey (ACA) should be a starting point for data collection about people with disabilities, since these questions have been widely tested and are in use in multiple government

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[14] 77 Fed. Reg. at 137211.

surveys. The ACS questions were also adopted as the data standard for disability status in the HHS/OMH survey standards.

Disability status information is critical for care team members to know, in order to provide patient-centered care that by definition must accommodate any ongoing, special needs an individual might have. Many disabilities, such as autism, dyslexia, and others are not readily apparent, but have great potential to impact care and patients' ability to follow through with self-care.   Accordingly, we strongly recommend that disability status be collected for at least 80 percent of unique patients as a core criterion in Stage 2.

Sexual Orientation and Gender Identity

Collecting confidential sexual orientation and gender identity data is crucial to improving the quality and efficiency of the health care that lesbian, gay, bisexual, and transgender (LGBT) people receive, and to addressing the significant health disparities that the LGBT population experiences. We strongly urge CMS and the Office of the National Coordinator for Health Information Technology (ONC) to begin planning for the collection of gender identity and sexual orientation data as part of the demographic data required for Stage 3.

D. We urge CMS to require that EPs and EHs demonstrate the use of this demographic information in conjunction with existing criteria to reduce disparities.

Collection of demographic data is limited in its value if it is not used, and collection only breeds mistrust among patients and lack of buy-in on the part of providers if it is collected without a clear use that brings benefit to all. Therefore <u>we strongly urge CMS to require this data to be USED to improve care for all populations and to reduce health disparities in a much more direct way</u>. There are many opportunities to do this in the proposed rule, including <u>generating reports by condition</u> and <u>stratification of quality measures by disparity variables</u>.[15]

Require that Providers Stratify Clinical Quality Measures by Demographic Data

<u>CMS should require that providers stratify clinical quality measures by demographic data.</u> Monitoring quality metrics by demographic variables will reveal specific disparities in care among provider's patient populations and help providers create strategies to reduce and eliminate such disparities. In ambulatory settings, the use of National Quality Forum (NQF)-endorsed "disparities-sensitive" measures should be recorded and stratified, at a minimum. NQF has also expanded its work on disparities from ambulatory care measures with a project developing Healthcare Disparities and Cultural Competency Consensus Standards. The standards are currently undergoing public comment and should be finalized later this year. CMS should work to implement these standards upon NQF endorsement.

Generating lists of patients

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[15] 77 Fed. Reg. at 13711.

CMS should link the "generate lists of patients" criterion to the requirement to collect demographic data. These lists of patients could be stratified by demographics in order to quantify the prevalence of certain diagnoses in sub-populations of a specific patient population. These lists could be made even more useful by then comparing sub-populations on quality metrics, which would help identify the contributors to disparities in care in a particular practice, which in turn would enable the practice to devise strategies for eliminating the identified disparities. Eventually, CMS should aim to be able to report lists by multiple demographic variables (for example, differences between Spanish-speaking Hispanics vs. English-speaking Hispanics or women with and without disabilities) to better understand and address health disparities.

Require Providers to Use Language Data to Provide Access to Meaningful, Useful Information

Collection of language data will have a dual purpose – allowing an analysis to identify any disparities and prevent discrimination, as discussed above, as well as service planning so that language services are in place for LEP patients. Almost 20 percent of the population speaks a language other than English at home. More than 24 million, or 8.7 percent of the population, speak English less than very well and should be considered LEP for health care purposes.[16] Numerous studies have documented the problems associated with a lack of language services, including one by the Institute of Medicine, which stated that:

> Language barriers may affect the delivery of adequate care through poor exchange of information, loss of important cultural information, misunderstanding of physician instruction, poor shared decision-making, or ethical compromises (e.g. difficulty obtaining informed consent). Linguistic difficulties may also result in decreased adherence with medication regimes, poor appointment attendance, and decreased satisfaction with services. (Cites omitted.)[17]

Thus, we believe that once language needs are recorded, EHR incentive recipients must provide information to patients in a language that they understand. For example, patient reminders must be provided in the patient's language when a language is noted. Again, this is a critical piece to ensure that we move beyond mere data collection to a meaningful use of this data that will ensure LEP patients have access to care and providers can meet the needs of LEP patients. It will also ensure these providers comply with existing civil rights laws as discussed above.

Priority 4: Enabling New Payment and Delivery Models

Clinical Quality Measures

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[16] American Community Survey, 2006-2008, *Selected Social Characteristics in the United States: 2006-2008*; also American Community Survey, 2008, *Language Spoken at Home by Ability to Speak English for the Population 5 Years and Over,* Table B16001, *available at* http://factfinder.census.gov.
[17] Institute of Medicine, *Unequal Treatment: Confronting Racial and Ethnic Disparities in Health,* at 17 (2002).

A. Selection of a meaningful, parsimonious set of quality measures supported by health IT is critical for provider engagement and actual improvement of care.

We must measure what matters, and stop measuring things that don't. The domains of Clinical Quality Measures (CQMs) in the proposed rule align well with the HITPC policy priorities, the National Quality Strategy and the recommendations of the Quality Measures Workgroup of the HITPC. We believe they are the right "buckets" for guiding measure selection and future measure development.

Unfortunately, the proposed rule puts forth many CQMs that are inconsequential (i.e., those that reflect basic competencies, mask outcomes, allow providers to just check-the-box, are duplicative, are topped out). CMS should remove all of these types of measures from not only Meaningful Use, but also from other federal programs in order to advance quality improvement as well as program alignment. Examples of these kinds of measures include:

- NQF 0055: Diabetes Eye Exam
- NQF 0056: Diabetes: Foot Exam
- NQF 0062: Diabetes Urine Screening
- TBD: Chronic Wound Care: Use of Wet to Dry Dressings in Patients with Chronic Skin Ulcers
- NQF 0508: Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening
- NQF 0132 -- AMI-1-Aspirin at arrival for acute myocardial infarction (AMI)
- NQF 0136 – HF-1 Heart Failure (HF): Detailed Discharge Instructions
- NQF 0137 – AMI-3-ACEI or ARB for Left Ventricular Systolic Dysfunction- Acute Myocardial Infarction (AMI) Patients

High-value CQMs in the proposed rule that reflect outcomes, efficiency, and processes that are closely related to outcomes should be retained as part of the final list CMS adopts and should be advanced through other federal programs as well. Examples of measures to retain include:
- NQF 0312: Low-back pain: Use of Imaging Studies
- NQF 0097: Medication Reconciliation
- TBD: Functional status assessment for knee replacement and for hip replacement
- NQF 0710: Depression Remission at 12 Months
- NQF 0376 – Incidence of potentially preventable VTE
- NQF 0471 -- Cesarean Section
- NQF 0477 – Infant not Delivered at Appropriate Level of Care

B. Alignment is Important, but it Must Support New Payment and Delivery Models

While we support the concept of measure alignment across federal programs to reduce burden on providers, we are concerned that CMS' proposed strategy for alignment will dilute Meaningful Use. Meaningful Use must support new models of care, and therefore requiring Meaningful Use to adopt elements from legacy programs such as the Physician Quality

Reporting System (PQRS) is counterproductive. Instead, CMS should integrate the more progressive Meaningful Use CQM requirements into other federal programs.

We DO NOT support the proposal to give eligible providers credit for Meaningful Use by participating in PQRS, because most of the PQRS measures are not high-value measures, and electronic submission of them does not demonstrate Meaningful Use of EHRs. Others share this view, including the Measures Application Project (MAP)[18], convened by the National Quality Forum (NQF), which submitted a final report to Congress saying that this is a strategy that could be pursued when the PQRS program is more advanced than its current state. Moreover, the PQRS program is limited to Medicare Part B data, and Meaningful Use provides a much better opportunity for using multi-payer data for quality measurement.

Alignment with the private sector is also important for reducing provider burden and increasing the value of quality metrics for consumers. CMS misses the opportunity to effectively leverage measures being used in the private sector. For example, CMS:

- Does not include a measure of blood sugar control for patients with diabetes (which is a critical area for primary care) – it should use NCQA's intermediate outcome measure in this space.
- Proposes to use a new measure of "Adverse drug event prevention: outpatient therapeutic drug monitoring." However, this measure's definition is extremely similar to that of NCQA's "Annual monitoring for patients on persistent medications" measure. Based on this, CMS should look into using the NCQA measure instead. As specified in the proposed rule, CMS' measure is also misleadingly labeled, as it doesn't actually capture whether an adverse drug event was prevented.

We are not in favor of offering a widespread option for group reporting in Stage 2. We support the notion of group reporting as a means of offering flexibility and administrative efficiency to providers, and we support this option for providers who are operating as a team. However, given that the quality measurement and practice environments are just beginning an evolution to team-based care, it is premature to offer a group reporting option for the majority of eligible professionals. Simply put, there are few robust measures that genuinely reflect team-based care.

C. **Stage 2 of Meaningful Use has not yet begun to exercise functionalities that are essential to enable meaningful measures of the future.**

Reporting Options for Eligible Providers

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[18] "Measure Applications Partnership Pre-Rulemaking Report: Input on Measures Under Consideration by HHS for 2012 Rulemaking," accessed at http://www.qualityforum.org/Setting_Priorities/Partnership/Measure_Applications_Partnership.aspx

None of the options for reporting proposed in the NPRM are ideal. Of the proposed reporting options, we recommend the following to most effectively leverage quality measurement in Stage 2 Meaningful Use.

1. Make Option 1A[19] available for specialists, in an attempt to make Meaningful Use as relevant to their practice as possible.
2. For individual primary care providers and group reporting for providers acting as a medical home (primary care, pediatrics, obstetrics and gynecology), we would recommend option 1B. [20]
3. Make the Medicare Shared Savings Program and Pioneer ACO model group reporting option available for primary care **IF** CMS expands sample size requirements to generate meaningful performance information for individual clinicians.

Current measurement sets are inadequate for purposes of supporting new payment and delivery models, and new measures that are enabled by the benefits of health IT have yet to be developed. In fact, the measurement concepts that exhibit the most significant gaps (care coordination, patient engagement, patient-focused outcomes and efficiency) generally require functionalities that are only possible in an electronic environment, and are among the measure concepts most critical for supporting new payment models.

We believe that the EHR Incentive program is a unique opportunity to address measurement gaps. CMS could promote rapid-cycle measure development by encouraging eligible providers (with a focus on specialists) to test and report on measures that meet robust criteria in each of the 6 domains identified by the HIT Policy Committee and its Quality Measures work group.[21] This sort of real-world testing is a critical part of the endorsement process, and meaningful use provides a safe place for providers and vendors to work together to ensure the full benefit of health IT in the quality measurement arena. In addition, testing new measures as a byproduct of practice encourages the use of real-time, clinical data, rather than retrospective claims, for assessment of performance. Finally, an essential benefit of testing measures as part of the MU process is that it would be done in the electronic environment in which these new measures will be implemented, rather than re-tooling a measure designed for the paper world. Meaningful Use provides an opportunity for a more rapid, iterative measure development process, supported by health IT.

Hospital Reporting Threshold

Of the four options for patient population proposed by CMS, [22] CMS should adopt an "all patients – all payer" approach, given the efficiencies and significant decrease in burden for

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[19] 77 Fed. Reg. at 13746.
[20] 77 Fed. Reg. at 13746.
[21] Patient and Family Engagement; Patient Safety; Care Coordination; Population and Public Health; Efficient Use of Healthcare Resources; and Clinical Process/Effectiveness
[22] 77 Fed. Reg. at 13764.

providers that will be characteristic of a quality measurement infrastructure supported by technology.

Conclusion

As consumer and patient advocates, we appreciate the opportunity to provide input on the advancement of the EHR Incentive Program. By building in criteria that support the NQS and empower patients and families, we can achieve the common vision of a patient-centered health care system that delivers the right care, at the right time, in the right setting. If we do not, we will not sufficiently improve health outcomes and reduce costs to meet the goals of the Affordable Care Act. We strongly urge you to issue a strong final rule, leveraging the additional year before Stage 2 begins to make robust advancements in the criteria over Stage 1.

Thank you for considering our comments. We look forward to working with you to ensure the evolving definition of Meaningful Use delivers on the promise to help transform our health care system into one that puts patients and families first.

Sincerely,

Members of the Consumer Partnership for eHealth and the Campaign for Better Care

Advocacy for Patients with Chronic Illness, Inc.
AARP
American Association on Health and Disability
American Hospice Foundation
Caring From a Distance
Childbirth Connection
The Children's Partnership
Colorado Consumer Health Initiative
Community Service Society of New York
Connecticut Health Policy Project
Consumers Union of the United States
The Empowered Patient Coalition
Family Caregiver Alliance
Futures Without Violence, formerly the Family Violence Prevention Fund
Healthwise
Medical Advocacy Mural Project
Mothers Against Medical Error
National Consumers League
National Health Law Program (NHeLP)
National Partnership for Women & Families
National Women's Health Network
OWL – The Voice of Midlife and Older Women
SEIU

Universal Health Care Action Network (UHCAN) of Ohio
The Well Spouse Association