

March 15, 2010

Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

**File Code: CMS-0033-P (Medicare and Medicaid Programs; Electronic Health Record Incentive Program Proposed Rule)**

**RE: Comments on the Proposed Rule for Incentive Payments to Providers, as per the American Recovery and Reinvestment Act of 2009**

Dear Ms. Frizzera:

The 21 undersigned consumer, labor union and employer organizations appreciate the opportunity to comment on the Meaningful Use proposed regulations. We believe CMS strikes the correct balance between setting the bar at a level where health care transformation can be achieved, while at the same time implementing change in a staged process that allows for the objectives to be reasonably met by our nation's providers. But unless the meaningful use incentives result in measureable improvements for consumers and their experience with the health care system, this enormous investment risks being futile.

**In particular, we want to voice our support for how the proposed rule accomplishes the following:**

- **Strongly supports a patient-centered view of health care:** Overall, CMS' proposed rule would support the transformation of the health care system – via HIT – into one where all patients have the information and tools they need to be fully engaged in their care, and providers have real time access to medical information and tools to improve quality and safety, with an eye toward improved access and elimination of health care disparities.
- **Offers providers flexibility, yet retains patient privacy and security:** We applaud the flexibility afforded providers in stage 1 of the program, and believe that the strategies CMS proposes – including the 90-day requirement in the first year, the phased implementation of the criteria over five years, and assistance through vehicles such as the Regional Extension Centers, the National Research Center, the state HIE grants, the BEACON communities, and the SHARP program – will allay concerns that the requirements are too ambitious. At the same time, we urge you to hold inviolate the patient privacy and security standards written into the proposed rule.
- **Appropriately uses clinical quality measurement:** We fully support the use of clinical quality measurement as a means of determining whether Eligible Providers (EPs) and Eligible Hospitals are using HIT in a meaningful way. CMS has taken providers' concerns into consideration in two very important ways – namely, by choosing many NQF-endorsed measures that are already being used in the PQRI and RHPDAPU programs, and by allowing

- reporting via attestation in 2011 – to ensure that the quality reporting component of the incentive program is feasible to implement.
- **Makes appropriate allowances for the current state of technology infrastructure:** We believe that standards, technology and infrastructure are sufficiently in place to allow providers to meet the 2011 criteria for incentive payments, and that CMS has made generous accommodations to the concerns voiced by some providers. CMS has committed to enhancing its capability to collect EHR-transmitted data, and we hope providers will view this effort to develop systems that will be able to accept such data over the next two years as a sign of the nation's largest purchaser of health care's strong commitment to the creation of a transformed health care system.
  - **Will result in vast improvements in data collection and understanding of how care is delivered:** We applaud CMS' decision to require that eligible hospitals report on all EHR incentive clinical quality measures for which they have applicable cases, without regard to payer, and further, to require all Medicare eligible hospitals participating in the program to report on Medicaid measures for which the hospital has applicable cases. Having an electronic database of quality measures created with all-payer data will help providers, policymakers, and other stakeholders gain a more complete picture of patients' experience in the health care system, advancing our ability to make policy decisions, target investments, reduce health care disparities, and set standards for quality improvement.

**Consumers, labor unions, and employers voice our strong support for this proposed rule, and urge CMS to stand strong in the face of opposition from providers. The criteria you have proposed to assess meaningful use are vital to the public interest and should not be slowed or reduced.**

The following comments focus on 1) elements of the proposed rule where we believe improvements are necessary in order to fully realize the purpose of the HITECH program; and 2) a vision for the future of the HITECH program and the meaningful use definition, for consideration in preparation of the 2013 and 2015 rules and regulations.

#### **CONSIDERATIONS FOR IMPROVING THE 2011 CRITERIA**

From the perspective of consumers and purchasers, the proposed measures of clinical quality represent a good set, although some minor improvements could be helpful in Stage 1 and substantial improvements are needed in future Stages. Our recommendations include the following:

- **Re-define the Content of the Core Measure Set:** We support the idea of a core set of measures; however, the three measures listed in Table 4 of the proposed rule (inquiry regarding tobacco use, blood pressure measurement, and drugs to be avoided in the elderly) are not strong or meaningful enough to produce the type of information that consumers and purchasers want to know across all specialties. We encourage CMS to require that these three measures be reported by all specialties to which they are appropriate in 2011, and that CMS develop a different core measure set for 2013. The undersigned organizations will work with CMS to develop a more meaningful set of core measures that will achieve the original intent of this concept in time for the next proposed rule.
- **Reinstate Measures of Efficiency in Stage 1:** As the HIT Policy Committee recommended, we urge CMS to require eligible providers and hospitals to measure efficiency in two ways: 1) by using EHRs to record the rate of prescribing of generic medications; and 2) by coding indications for high-cost imaging services. Recording the prescription of generic medications via EHR will allow the final meaningful use definition to meet the standard set by the CBO, which stated that one of the benefits of EHRs is their ability to promote the use of cost-effective generics. Adding this element to the EHR requirements is feasible within the current technology environment, and would not pose a burden on providers. In Stage 1, we would not recommend setting a threshold that providers need to meet on this measure.

In regard to high-cost imaging services, if we are to create a system in which overuse is reduced via HIT, it will be critical to understand why high-cost imaging procedures are ordered. CMS can collect this information by amending the requirement that EPs and eligible hospitals “implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering,” to “implement five clinical decision support rules relevant to specialty or high clinical priority, *at least one of which should be aimed at improving the efficiency of diagnostic testing or the ordering of appropriate treatment.*”

- **Reinstate Advance Directives in EHRs:** We strongly urge CMS to reinstate the requirement that providers document the presence or absence of an advance directive in patients’ EHRs, in stage 1. This element was recommended originally during the draft definition process by the Meaningful Use workgroup to the ONC HIT Policy Committee and we believe it would be a major opportunity missed if it is not added back in. The argument for taking it out – that there are too many providers for whom it is not appropriate to ask their patients for this information – could be easily rectified by adding it to the measure requirements for those specialists and primary care providers for whom it would be appropriate. From a consumer perspective, recording the existence of an advance directive reflects a provider’s efforts at care coordination, as well as offering a clear example of how actively a patient and his/her family and caregivers are engaged in the decision-making surrounding their health care. In the absence of strong patient engagement measures, the recording of an advance directive is a strong indication of patient engagement. Consumers and purchasers know that a health care system where providers communicate with their patients leads to higher quality care, often at a lower cost.
- **Reinstate Patient Education Criteria:** The HIT Policy Committee recommended that providers should meet criteria to provide access to patient specific educational resources. This is not reflected in the proposed rule and we strongly urge CMS to add it in. Patients and caregivers need patient-specific education and resource materials if they are going to better understand and use the information given to them to make decisions and self-manage their care. Again, it is an opportunity lost if providers are not required to meet this criterion, given that HIT systems are already able to provide this information through linkages with Medline Plus and other well-vetted content providers. Providers do not need to implement an HIT system that has education content generating capability to meet this criterion. They can use information already collected via the EHR to manually generate information for patients.
- **Require Use, Not Just Collection, of Race, Ethnicity, Language, and Gender (RELG) Data:** We applaud the proposed rule’s requirement that eligible providers and eligible hospitals record patient demographic data, including RELG. However, if this data is to actually improve patient care it must be analyzed and used. Two ways in which this can occur include 1) stratify quality data by RELG in order to identify gaps and disparities in care; and 2) require that when providers meet the objective of generating lists of patients by specific conditions, that they stratify these lists by race, ethnicity, gender and language. To achieve the goals of this program, EPs and eligible hospitals should attest that they make use of these stratified reports in order to determine how effective their practices are at reducing disparities.
- **Incorporate Registry Data:** To fully realize the power of the data collected via HITECH, we urge CMS to consider opportunities for integrating the data collected and submitted by providers with already-existing registry data. Registry data provides information about patients over time (e.g. from hospital, to surgeon, to post treatment, to outcomes). CMS has already indicated its interest in having hospitals participate in registries, as evidenced by the addition of registry participation measures in RHQDAPU. CMS has also made clear its desire to align the measurement collection implemented via HITECH with the PQRI and RHQDAPU programs. Creating a strategy for integrating registry data into HITECH will be a natural extension of all of these efforts. By integrating this data, the definition will meet the

information sharing goal of meaningful use, and move the field away from perpetuating the current environment in which data often exists in silos. This is particularly important as we move into delivery and payment models such as Accountable Care Organizations (ACOs), and the use of episodes of care for payment.

#### **VISION FOR THE NEXT THREE YEARS OF HITECH**

The HITECH program and its meaningful use incentives should create a new generation of quality measures in areas that are currently extremely challenging, including efficiency, care coordination, and outcomes. We urge CMS to strengthen the role of quality measurement within the context of an electronic environment by encouraging the following:

- **Focus on a streamlined set of meaningful measures:** The measures in Tables 5-21 of the proposed rule are a good initial set from which to launch this program. In expanding the list of measures in future years, we strongly urge CMS to focus on outcome measures, or at the very least, on processes that are directly related to outcomes such as mortality, morbidity, healthcare-acquired conditions, readmissions, and functional status. We also urge the inclusion of measures linked to gaining a better understanding of patients' experience of care, care coordination, or efficiency. We believe that measurement and acting on the results of such measurement is an important aspect to improving quality.

The use of EHRs to collect data will give providers and CMS an incredible opportunity to utilize measures that rely on clinical data, as opposed to the administrative and billing data that are commonly utilized today. This ability should allow CMS to move beyond process measures, and use (and develop) measures of clinical quality and outcomes that rely on coded clinical data.

Thus, for 2013 and beyond, the quality measures used to assess meaningful use should:

- Have a high impact on how care is delivered
- Address gaps previously identified in both the PQRI and RHQDAPU programs
- Be relevant to consumers and purchasers, such as outcome and resource use measures
- Reflect the continuum of care and encourage care coordination
- Address appropriateness of care
- Be designed to allow for assessing and reporting on disparities of care

It is clear from the proposed list of measures that some of these criteria were considered for the 2011-2012 reporting period. As with the core measure set, representatives of the undersigned organizations would be happy to work with CMS in thinking about the expanded set of measures.

- **Expansion of Measures in Select Clinical Areas:** The proposed rule notes that for 2013 and 2015, CMS will look to expand the number of measures required for EPs and eligible hospitals to report. We recommend that this expansion focus in areas that currently lack measurement depth, but for which consumers and purchasers now spend most of their health care dollars, including pediatrics, long-term care, obstetrics and gynecology, oral health, and mental health and substance abuse.

One example of where CMS can fill this gap is by adding two perinatal care measures to those required of eligible hospitals, to reflect the volume of hospital admissions related to childbirth:

- Elective Delivery Prior to 39 Weeks Gestation
- Exclusive Breastfeeding During Birth Hospitalization

These measures were endorsed by the National Quality Forum in October, 2008 to capture data on two processes that are directly related to health outcomes and costs.

- **Increase Measures of Care Coordination:** For 2011-2012, the proposed definition uses measures of medication reconciliation to assess care coordination. The National Quality Forum recently endorsed a series of care coordination measures, which could be included in 2013. They can also be used as a starting point for developing better measures that truly allow for providers and patients to know if care transitions and other loops are closed in the care coordination process, via the use of EHR technology.
- **Include Other Measures Related to National Priorities Partnership Goals:** The meaningful use definition was written with the NPP goals as a foundation. We urge CMS to add measures that support these goals, and demonstrate such indicators as reduction in medical errors and improvements in patient safety; use of evidence to reduce overuse of procedures, and reduction in disparities through the use – and NOT just the recording – of race, ethnicity, language and gender (RELG) data
- **Make HIT Truly Meaningful to Consumers and Purchasers:** The current definition of meaningful use focuses – appropriately – on specific goals, objectives, and measures to determine whether those objectives are met. However, this reflects a very silo'd view of the system. As HIT becomes more engrained in the fabric of our health care system, we envision the ability to move beyond this silo'd perspective to understand whether the health care system is truly meeting consumers' and purchasers' needs. We urge CMS to determine whether greater use of HIT through EHRs and Personal Health Records (PHRs) is positively affecting consumers' experience at the point of care, by measuring changes in how patients are actually experiencing care. Until we understand how consumers are reacting to the implementation of HIT, we will not truly recognize the investment being made by HITECH.

On behalf of the millions of Americans represented by the undersigned organizations, thank you for your efforts and your responsiveness to our comments. If you have any questions, please contact either of the Disclosure Project's co-chairs, Peter V. Lee, Executive Director for National Health Policy at the Pacific Business Group on Health, or Debra L. Ness, President of the National Partnership for Women & Families.

Sincerely,

American Benefits Council  
Bridges to Excellence  
Buyers Health Care Action Group  
Center for Advancing Health  
Childbirth Connection  
Consumers Union  
Employers' Health Coalition  
Health Care Incentives Improvement Institute  
Healthcare 21 Business Coalition  
Health Policy Corporation of Iowa  
Iowa Health Buyers Alliance  
Massachusetts Group Insurance Commission  
National Business Coalition on Health  
National Retail Federation  
New York Business Group on Health  
National Partnership for Women & Families  
Pacific Business Group on Health  
Prometheus Payment  
Service Employees International Union  
The Leapfrog Group  
Xerox