May 7, 2012

Marilyn Tavenner

Administrator

Centers for Medicare and Medicaid Services

Department of Health and Human Services

Attention: CMS–0044–P

P.O. Box 8013

Baltimore MD 21244–8013

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

**RE: CMS-0044-P**

Dear Administrator Tavenner:

The undersigned organizations and members of the Health IT Now Coalition are pleased to respond to the Medicare and Medicaid Programs; Electronic Health Record Incentive Program – Stage 2 Notice of Proposed Rulemaking published in the *Federal Register* on March 7, 2012. Health IT Now (HITN, www.healthitnow.org) is a diverse coalition of 65 organizations, including health care providers, patient advocates, consumers, employers and payers, who support the adoption of health IT to lower costs while improving quality, safety and clinical outcomes. Other organizations have joined our comment letter to highlight the importance of this issue.

We believe the NPRM is a solid first step in promoting information exchange and care coordination. We call on CMS to strengthen the NPRM to facilitate robust interoperability and information exchange. Specifically, we recommend:

1. Ending information exchange blocking;
2. Adopting more robust interoperability standards;
3. Promoting greater patient engagement; and,
4. Coordinating quality measures across Medicare and Medicaid.

In recent years, the Administration and Congress, as well as the patient, provider, payer, and employer communities, have expressed strong, bipartisan, industry-wide support for better care coordination using electronic record systems that share clinical information. Medicare, Medicaid and the private sector are working to implement ACOs, medical homes, hospital readmission-prevention programs and other models that rely on data sharing. We believe the current and proposed Meaningful Use standards are not adequate to support these initiatives. CMS has an opportunity to build on the foundation created by the NPRM to support the current and ongoing implementation of these care models.

We are concerned CMS’ proposal to delay implementation of Stage 2 by one year for EPs and EHs who became Meaningful Users in 2011 could squander an important opportunity to improve interoperability in 2013, when Stage 2 would have originally started. Although we recognize that the delay addresses practical concerns, it concedes too much. We also support clearly defining the role of HIEs in the NPRM as a way to address some of the seemingly intractable policy and operation problems associated with quality metrics, interoperability requirements, information blocking and patient engagement. We strongly encourage CMS to take bold steps and use every policy lever at the Agency’s disposal to aggressively implement interoperability standards and rules for exchange that promote coordinated care models in 2013 and beyond. We provide our comments and recommendations below.

**I. End Data Blocking**

Some EHR vendors and healthcare organizations actively block information exchange between providers and even within institutions. Business models built around such data silos have no place in a healthcare system experiencing the challenges currently faced in this country. The Meaningful Use program, which is intended to facilitate health information exchange for the public good, should apply policy levers to challenges not just of standards but governance to ensure this practice does not continue.

Accordingly, we encourage CMS to:

* Instruct ONC-ACBs to decertify EHR vendor products on a case-by-case basis if the product cannot perform the function as certified due to policies or other efforts to block information exchange made by the vendor.
* Require makers of EHR products to certify that their products do not block information exchange under EHR certification standards in 2014 and can reliably perform the functionality to which they have been certified. EHR vendors who pursue blocking strategies through one or more products should likewise be decertified.
* When an exchange failure is reported to an ONC-ACB and it has been determined that it was not due to a technology issue, but rather a provider practice, those healthcare professionals or organizations should then be made ineligible for the program.
* Include electronic submission of consolidated CDA to HIEs to create a minimum repository of standard health information that supports shared viewing of current health information across providers, institutions, patients and caregivers.

**II. Learn Where Exchange Problems Exist and How to Correct Them**

For 2013, CMS is proposing to eliminate the current test for exchange of clinical data, because the Department found the requirement to be “surprisingly difficult for providers to understand”. CMS requested comments on four options, including moving to actual electronic submission of a summary of care document for a real patient either to another provider of care at a transition or referral or to a patient authorized entity.

We support maintaining the test of clinical exchange because it will provide CMS with a valuable tool to determine where exchange problems exist and how to correct them. Likewise, retaining the test will allow providers to know if their systems work, and it will assist them in better understanding the necessary workflow changes that might be required by the more robust Stage 2 requirements. We suggest reporting data exchange test results, even unsuccessful ones, to ONC-ACBs. Any unsuccessful test would include the details of test and the reason for failure. This reporting could be similar to the error reporting system used by Microsoft Office. ONC and software vendors would then have actual data with which to address any emerging problems.

**III. Promote Systemic Interoperability**

Promoting a longitudinal EHR for each patient – enabled by a networked information model for sharing and querying of data residing in multiple locations – is a critical component of the effort to lower costs and promote better patient outcomes.

*Summary-of-Care Record*

The NPRM requires a patient’s summary of care record be provided for more than 65 percent of transitions of care and referrals, but it does not require the record to be provided electronically. The NPRM also requires an electronic transmission of the summary-of-care record for more than 10 percent of transitions of care or referrals to legally-distinct organizations using an EHR from a different vendor. We support these requirements as a bare minimum to promote care coordination in Stage 2. In addition, the measure is imminently achievable. In 2010, according to AHA survey data, 19 percent of hospitals were sharing patient clinical information electronically with ambulatory providers outside their system.

We suggest CMS make the following refinements to the NPRM:

* Require the summary-of-care document be sent electronically and recorded as part of the patient’s EHR.
* Ensure the summary-of-care document is generated automatically for all summaries. We support moving the requirement from 65 percent to 80 percent.
* Retain or expand the 10 percent requirement. This is the only electronic exchange required across unaffiliated providers in 2014. Half of all providers may be meaningful users in 2014 and it is reasonable to expect electronic exchange between those participating in the program.
* Require EPs and EHs to demonstrate participation in an HIE as a requirement in Stage 2 through a provider participation agreement. The Stage 2 exchange requirement should recognize exchanges through an HIE, rather than exclusively through the Direct protocol. This approach would reduce burdens on providers who are required under the rule to develop a separate operating platform to enable Direct exchange.
* All participants in the health continuum, including pharmacists, labs, pathologists, mental health providers, payers and others, should be encouraged to participate in the HIE to provide a more complete view of a patient’s history. These entities supply significant amounts of critical health information, yet many are excluded from the program.

*Transport Standards Related to Summary of Care Record*

As part of the NPRM, CMS is proposing to limit the numerator for the second measure (the 10 percent requirement) to only count electronic transmissions that conform to the standards proposed for adoption at 45 CFR 170.202 (Direct, Direct Plus and SOAP) of the ONC Standards and Certification rule. These are “push” transport standards that allow point-to-point exchange of information, similar to secure email. CMS has requested comments on the appropriateness of limiting this measure to only those standards finalized by ONC. We oppose limiting the numerator to the protocols outlined by ONC.

While the Direct protocol may be desirable in certain ways because of its greater potential for adoption, requiring it as an exclusive standard frustrates providers who are already using alternate standards. This policy devalues the time and resources many have made in moving beyond simple point-to-point messaging, forcing them to redesign their more robust systems to meet the Direct protocol. Our further concerns include:

* While rapidly implementable, the Direct standard is minimally scalable and would likely lack the data liquidity necessary to enable health IT dependent models, such as ACOs and medical homes.
* The Direct standard is good at sending discrete information, but it simply does not deliver the aggregated information necessary to assist the delivery of care in coordinated settings. This creates patient safety issues since one clinician’s view of the patient encounter may be limited. A summary of care record established at the local HIE level could provide a better, more up-to-date view of a patient’s history.
* There are several ways providers interact with HIEs that are not sufficiently supported by Direct: records may be exchanged point to point, sent through a Health Information Exchange organization or published to a condition-specific registry operated by a professional society or patient organization. To service these use cases, we believe NwHIN Exchange standards should be an acceptable demonstration of the electronic exchange measurement.

Direct is an important step in fostering information sharing between providers, but Direct should be a floor, not a floor and a ceiling. We suggest allowing for backwards compatibility to the standards and recognizing all standards-based information exchanges in the numerator of the measure. Doing so would allow health care providers to use transport standards that allow both sharing and querying of data residing in multiple locations. Backward compatibility standards allow the market to evolve without federal rulemaking, but they still support the approach ONC and CMS are pursuing through separate rules. We urge CMS to recognize this potential by not adopting an exclusive numerator in the final rule.

**IV. Other Information Exchange Standards**

 Meaningful Use requirements other than the summary-of-care record exchange also facilitate the use of key clinical information for care coordination and cost management. We offer the following suggestions on these measures:

1. **eRx:** We support moving the percentage of prescriptions written electronically from 40 to 65 percent. RxNorm should be the required terminology standard. We also support requiring the check of the script against at least one drug formulary. The comparison to at least one drug formulary would be made easier if CMS and ONC adopted standard vocabulary for all eRx. We recommend that ONC adopt insurance eligibility checks and claims status transactions as a function of EHRs to enable patient specific matching to specific plan formularies.
2. **Laboratory Data:** CMS has proposed including laboratory results “where results are available as structured data”. We support moving the measure to a core requirement and raising the compliance threshold to 90 percent, considering 2009 baseline measure of use according to the CDC is 95.5 percent. A large number of clinical lab results are generated by hospitals using proprietary codes. To facilitate the utility of such information and the higher threshold, we suggest requiring that lab results be sent in LOINC format.
3. **Public Health:** We support the ongoing submission of reportable public health measures to public health departments (reportable lab results, immunizations and syndromic surveillance) and to HIEs, and for making such reporting a core requirement in Stage 2. To facilitate reporting, we support counting as compliance any successful submission using any standard that is backwards compatible to the standards proposed to be adopted by ONC. There are, however, no standard specifications for the transmission of the reports intended to go to the public health departments and registries, which means the burden of reporting will fall on providers. We recommend that the ONC work with the National Library of Medicine (NLM) and other public health audiences to identify ways to improve the adoption of the implementation guides (content and transmission specifications) by the various registries.
4. **Reporting to Cancer and Other Registries:** We support these additions as an effective tool to promote patient and population health. The inclusion of more registries will promote participation of specialty providers. We encourage CMS to work with these groups in expanding the range of diseases covered. There are, however, no standard specifications for the transmission of the reports intended to go to the public health departments and registries which means the reporting burden will fall on providers. We recommend that the ONC work with NLM and other public health audiences to identify ways to improve the adoption of the implementation guides (content and transmission specifications) by the various registries.
5. **Medication Reconciliation:** We support moving this from menu to core and increasing the percentage requirement.   The requirement allows for reconciliation based on patient interviews and not actual patient data, however.  Because patients often are not the best historians of their medication usage, we suggest the medication reconciliation be performed based on actual drug data and should thus be linked to the summary of care record, eRx and active medication list requirements.  Our proposal is particularly important for providers, such as Community Mental Health Centers, that do not participate in the program for statutory reasons. More than 90% of their caseloads consist of patients on psychotropic drug regimens (typically composed of four or more products) who are at risk of adverse clinical outcomes when medication reconciliation does not actively involve primary care doctors and medical specialties.
6. **Imaging Results:** We support making imaging results available through EHRs and requiring that they be transmitted through electronic exchange. The exchange of images is significantly more advanced than other clinical information, so we support adding a requirement that 10 percent of all scans and tests be exchanged electronically.
7. **Hospital Medication Orders:** We agree that hospitals should track medications from order to administration using an electronic medication administration record (eMAR). eMAR has been shown to improve patient safety and outcomes and to lower costs.

**V. Engage Patients and Families in Their Care**

A key path to better health care is engaging patients in their care by facilitating electronic access to their information. We support the NPRM measures but recommend several improvements that would make them more workable for both patients and providers:

1. **View, Download and Transmit:**  We support this measure as a core objective because it aligns with IT tools in other sectors, such as the financial services industry.   We are concerned that portals will not be useful if patients do not know how to use them, and this could inadvertently penalize providers who deliver care in an area with below average online access. To this end, we believe that the number of patients that register to use the portal should be the threshold for EPs and EHs on this measure.  This approach will not only increase patient access to data but will incite providers to promote patient engagement in their care.
2. **Secure Messaging:** We support including secure messaging as a core objective in 2014. Messaging is inexpensive and will foster better communication, access and coordination between providers and patients. However, we suggest that it is not necessary to count the number of messages from patients but rather focus more on the providers’ behavior. An alternative approach would be to instead require that the EP and his/her staff send a message to at least 25% of patients (a higher threshold than the original because it’s controllable by the EP) or measure the percent of patient messages that an EP or staff respond to with a high associated threshold. To facilitate communication, the response to the patient should be in the same form as the message from the patient.
3. **Clinical Summaries:**  CMS proposes to require EPs, EHs and CAHs to provide clinical summaries to patients within 24 hours for more than 50 percent of office visits. We believe 36 hours is a more appropriate length of time. This would allow for clinical notes to be added to the record based on a patient encounter.
4. **Patient Reminders:** We support making patient reminders a core requirement for Stage 2. We also support raising the compliance threshold above 50 percent. CMS should consider standards that denote in a record when the provider responsibility of patient reminders has been transitioned to another provider and allow the transitioning provider to be excluded from the measure.
5. **Patient Education Resources:** We support providing educational resources to patients, and encourage CMS to also require the inclusion of relevant clinical trial opportunities.
6. **Family Health History:** We strongly support the inclusion of Family Health History as structured data into patient records. Recording a family history is a low cost and highly effective diagnostic test to determine a patient’s risk factors for inherited conditions and inform clinical decision-making. It is an effective mechanism for getting patients engaged in their health. CMS should constrain this requirement to one or more first-degree relatives that have been affected by inheritable chronic conditions such as cancer, heart disease and type II diabetes.

**VI. Coordinate Standards and Encourage Integration Across Programs**

ACOs, medical homes, hospital readmission programs and other delivery reform efforts require strong standards for interoperability and quality measurement that are coordinated across CMS programs. Alignment of clinical quality measures will make the reporting of CQMs less burdensome.

1. **Clinical Decision Support**. CDS alerts should be patient-specific, actionable based on the clinical profile of the patient, and targeted to the provider best positioned to act on the information.
2. **Alignment Across Programs**. We support CMS’ effort to align the program reporting requirements across physician and hospital reporting and in the ACO program. We recommend CMS adopt all the clinical quality measures used in the Shared Savings Program for the Meaningful Use program, as it will promote participation in both.
3. **Clinical Quality Measures**. We suggest focusing more on outcomes measures and less on process measures. Some measures in the proposed rule represent basic standards of care and will have little impact on outcomes. Other measures for overuse are not included in the core set, but should be (see, for example, NQF 0210, NQF 0212, NQF 0213, NQF 0309, and NQF 0602).
4. **Computable Performance Measures.** Meaningful use quality measures should be reasonably and uniformly calculated within the context of certified EHRs. This will simplify the reporting requirements by automatically generating reports based on data within the EHR.

**VII. Conclusion**

We appreciate the opportunity to provide you with our comments on the proposed modifications to the Meaningful Use program. CMS has proposed an excellent start to the development of an information-rich and care-coordinated environment. We encourage you to more aggressively promote interoperability and health IT adoption in general to ensure the program reaches its optimal potential to improve outcomes and lower costs. We stand ready to work with you to help ensure quality is improved and costs are reduced across the health system through robust clinical information sharing and interoperability.

Sincerely,

American Heart Association/American Stroke Association

Bread for the City

DC Primary Care Association

Intel Corporation

HealthHIV

National Alliance on Mental Illness

National Association of Health Underwriters

National Association of Manufacturers

National Council for Community Behavioral Healthcare

National Medical Association

National Organization for Rare Disorders

National Patient Advocate Foundation

Newborn Coalition

Pharmaceutical Care Management Association

Pharmacy e-Health Information Technology Collaborative

UnitedHealth Group

Verizon Communications

Veterans Health Council