

June 16, 2011

The Honorable Kathleen Sebelius  
Secretary  
U.S. Department of Health & Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Secretary Sebelius:

The role of health IT in supporting healthcare transformation is a critical topic of discussion this spring. Eligible professionals (EPs) and Eligible hospitals (EHs), and supportive organizations are working tirelessly to prepare for Stage 1 Meaningful Use of the Medicare and Medicaid Electronic Health Records (EHRs) Incentive Programs, as outlined in the Health Information Technology for Economic and Clinical Health Act (HITECH) provisions of the American Recovery and Reinvestment Act of 2009 (ARRA). The undersigned organizations request a meeting with you and the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator (ONC) senior leaders to discuss the issues identified in this letter.

In February, at HIMSS11 in Orlando, you encouraged the healthcare community to provide you answers for the following question: “Short of regulatory or legislative change, what are the top five solutions the U.S. Department of Health & Human Services (HHS) can implement to ensure greater success in meeting Meaningful Use Stage 1 for EPs and EHs?” Since that time, American Hospital Association (AHA), American Medical Association (AMA), Association of Medical Directors of Information Systems (AMDIS), College of Health Information Management Executives (CHIME), Electronic Health Record Association (EHRA), Federation of American Hospitals (FAH), and Healthcare Information and Management Systems Society (HIMSS), have collaborated to respond to your request and, based on subsequent consultation with our memberships, colleagues, and several members of the Authorized Testing and Certification Bodies (ATCB) Community, we have determined the five areas of greatest opportunity and challenge include:

- (1) Reduce Regulatory Complexity
- (2) Clarify Certification and Site Certification Processes
- (3) Address Providers’ Meaningful Use Resource Requirements
- (4) Clarify and Improve Registration, Attestation, and Compliance Processes
- (5) Evaluate Regulatory Timeline

At the outset, we wish to commend your Department, and in particular CMS and ONC, for your diligence in operationalizing these programs. Your team is carrying out a multitude of tasks necessary to implement this complex program, including the creation of educational tools, producing numerous Frequently Asked Questions (FAQs), dialoging with our members, and responding to inquiries on a range of topics.

The success of future stages will hinge on the outcomes and lessons learned from Meaningful Use Stage 1. Going forward, everyone realizes much remains to be done. To that point, we believe the collective efforts between the public and private sectors to address the five areas noted above will enhance EP and EH involvement in the Medicare and Medicaid EHR Incentive programs.

### **Reduce Regulatory Complexity**

Healthcare providers are in the midst of an enormous information system change. As these stakeholders attempt to become Meaningful Users, they are concurrently preparing for the conversion to new administrative transaction code sets and operating rules (ICD-10, 5010) and new Patient Protection and Affordable Care Act initiatives.

#### *Central Location for Meaningful Use Incentive Programs Guidance Needed*

The Medicare and Medicaid EHR Incentive Programs include large numbers of very specific requirements promulgated through regulation and sub-regulatory guidance. Healthcare providers and the vendors that serve them are often challenged in fully understanding and staying abreast of regulatory requirements for Certification and Meaningful Use requirements. Although sub-regulatory guidance may be available through town hall meetings, webinars, and in various locations on the ONC and CMS websites, the information is sometimes conflicting within and between sites, can be hard to find, and may be difficult to understand.

#### *Clarification on Use of Sub-Regulatory Guidance Needed*

An additional challenge arises regarding reliance on sub-regulatory guidance. Although FAQs can be very helpful in providing clarification on issues not addressed in sufficient detail in regulation, in practice some FAQs have resulted in uncertainty.

For example, the quality measure specifications have been updated since the final rule was published. However, there is no mechanism in place to notify users of updates to the quality measures program specifications. Additionally, a summary of the changes to the quality measure specifications was not provided with the updated documents, requiring users to compare the original version with the update to identify the changes. Therefore, some providers have used the measure specifications as originally published, while others have updated their systems based on the post-regulatory guidance. From a compliance perspective, the lack of specific guidance has made it unclear which approach is correct.

Given the transformative nature of the incentive programs and associated funding and legal obligations, the healthcare community needs authoritative, timely, unambiguous, clear information, and resources that address the policy and operational implications for EPs and EHs.

#### Proposed Solutions:

1. Launch a unified HHS website that serves as the “single source of truth” for CMS’s Meaningful Use and ONC’s Certification programs.
2. Launch “Meaningful Use and Health IT” checklist of tools detailing what each EP or EH needs to address, as well as linking to resources from the Health Information Technology Resource Center (HITRC), which should be publicly available to all.
3. Increase HHS efforts to provide a technical assistance resource for hospitals, similar to the Regional Extension Centers (RECs), focused on rural hospitals and those providing care to patients in underserved areas.

4. Extend REC services to specialist categories, and evaluate the effectiveness of the RECs' physician outreach and assistance efforts.
5. Establish a clear process to manage updates to specifications for quality measures, making sure that all published updates to quality measure specifications include release notes so users can easily identify what has been updated in the quality measure specifications. We ask that CMS provide clear guidance as to whether the implementation of the updated measure specifications is a requirement to meet incentives qualification, or is an optional update to qualify for incentive payments. We also urge HHS to include a process by which providers and vendors can access guidance on specific measures and their specifications as well as to provide feedback on problematic or unclear measures.

### **Clarify Certification and Site Certification Processes**

There is a growing level of confusion and frustration regarding elements of the certification process. In particular, complex scenarios can arise regarding modular certification and the treatment of the ancillary and non-certifiable IT applications that are often used with a certified system to meet EP or EH goals for quality, safety, efficiency, or data sharing. Our organizations are receiving numerous questions from members and customers on these issues, such as:

- What must one do to use certified EHRs modules independent of a complete system or when one's existing core system was certified as complete?
- Must one possess all software components or products used by the vendor to attest to use of certified Complete EHR?
- If a laboratory system interfaces data to an EHR, under what circumstance would the lab system need to be certified?
- What are the certification requirements for interfaces and interface engines?
- To demonstrate Meaningful Use, why do I need to "possess" technology I will not use?

Many of these issues have been generally addressed in ONC and CMS FAQs, often with considerable clarity. Due to the variability of individual provider and vendor situations, some uncertainty remains. We emphasize that these concerns pose an immediate challenge to providers seeking to be Meaningful Users, and there is opportunity and necessity to address the challenges now.

Several of the organizations who signed onto this letter have outlined the current challenges and possible approaches to addressing these issues. This analysis is included in the attached presentation, which will be separately conveyed to ONC, CMS, and the Implementation Workgroup of the Health IT Standards Committee.

#### **Proposed Solutions:**

1. Review the attached presentation articulating the observations and suggestions designed to foster greater understanding and compliance with the Certification Process and implement the proposed solutions as soon as possible.

## **Address Providers' Resource Requirements to Meet Meaningful Use**

The sheer volume and specificity of requirements for EPs and EHs, as well as the limited amount of information available to help them meet the requirements, is a cause for concern. To maximize the success of the EHR Incentive Programs, much can be learned from Stage 1.

### *Feedback Loop*

We believe it will be critical for CMS or ONC to create a mechanism for evaluating how Stage 1 is working; identifying barriers to compliance; and making the findings public. This need includes understanding when providers are having particular trouble meeting certain objectives or measures, whether existing thresholds are too high, if certain providers are lagging in compliance, or unable or unwilling to participate, and if cost is preventing some from participating. Understanding early lessons learned will be critical in establishing future requirements which are achievable.

### *Appeals Process*

The Stage 1 final rule outlined an appeals process for Medicaid providers. Although CMS indicated in the final rule their intention to establish an appeals process for Medicare providers, to date no details have been shared. We believe it is also critical that CMS establish a fair and straightforward process for providers who believe they have been inappropriately excluded from Meaningful Use eligibility or have received an incorrect incentive payment. We also believe that a more straightforward process is needed for EPs to determine whether they are "hospital-based". Today EPs must register first before learning if they are considered ineligible; they should have the opportunity to appeal these eligibility decisions and to alert CMS through a straightforward process when their status changes.

### *Synchronizing Incentive Programs*

Medicare has implemented a growing number of incentive and reporting programs that rely on submission of quality or use metrics from providers. These programs, such as the Physician Quality Reporting System (PQRS) program, the physician e-prescribing incentive program, the hospital inpatient quality reporting program (IQR), the readmissions reduction program, and the electronic health record (EHR) incentive program were created under separate federal laws and each includes unique eligibility criteria, incentive and penalty, and participation requirements. Better alignment among the programs is needed in order to reduce the regulatory burden on providers. While criteria for each program are already established in regulation, we believe more conversations are needed to review how these many programs can be better aligned in the future. Alignment may include both intentional overlap in reporting requirements, or limiting reporting on a given measure to a single program to avoid duplication.

### *Representation on Advisory Workgroups*

We believe the workgroups of the Health IT Policy Committee, in particular the Meaningful Use Workgroup, would be better served if there was greater representation by those who are developing and implementing systems and particularly those who understand the unique needs of small practices. According to an AMA survey, seventy-eight percent of office-based physicians in the U.S. are in a practice with nine physicians or less. The majority of those physicians are either in a solo practice or in a practice of between two and four physicians. Providers are a critical resource for providing input on how health IT can be used to improve practice workflow and enhance care processes and clinical decision-making. We are happy to recommend EPs who are willing to participate in and share their experiences and expertise at these workgroups.

#### Proposed Solutions:

1. Develop and conduct field surveys of EPs, EHs, and vendors to identify barriers and solutions that enhance participation in the Meaningful Use EHR Incentive Programs. The surveys would be most effective if conducted with both registered and non-registered EPs and EHs.
2. Engage the industry in a dialogue on recommendations to better synchronize the Meaningful Use, E-prescribing, PQRS, and IQR incentive programs.
3. Include greater representation of those who develop and implement EHRs on advisory workgroups, in particular the Meaningful Use Workgroup.
4. Engage the healthcare community to develop and collect feedback loop information.
5. Establish a Meaningful Use appeals process for Medicare providers.

#### **Clarify and Improve Registration, Attestation, and Compliance Processes**

We commend CMS for establishing the registration and attestation process under extremely challenging timeframes. We also recognize and applaud CMS for providing educational sessions and tools for providers in an effort to help them participate in the EHR incentive programs. However, the complexity of these processes requires even greater educational efforts and resolution of specific issues.

##### *Registration*

While some providers have found the registration process simple, others have encountered challenges that take weeks or even months to resolve. Providers are handed off to multiple offices, and spend undue effort trying to resolve data concerns.

##### *Attestation*

We appreciate the fact that CMS has recently clarified that providers need only attest to the fact that they have accurately transferred the quality measure results from their certified EHR technology. There was some concern and confusion over the component of the attestation process that requires providers to attest to the accuracy of the clinical quality measures, given issues with the development of the Clinical Quality Measures (CQM) and their roll-out into certified EHRs. In addition, given the large number of measures associated with the program and the inclusion of several measures that may require providers to calculate a denominator across both paper and electronic records, we are concerned that the 60 days provided after the end of the reporting year and before attestation must occur is inadequate and believe CMS should afford more time. Under the current hospital quality reporting program, for example, hospitals are provided more than 100 days to complete their reporting.

##### *Compliance*

The healthcare community would greatly benefit from clarification of the HHS audit and validation processes associated with the Meaningful Use attestation. Such clarification is needed regarding the possession of certified EHR technology, the meaning of each specific attestation statement, and specific documentation that will be required to support the attestation. To ensure such clarification addresses the questions of the healthcare community, we would be happy to assist in the development or review draft materials prior to publication.

Taking the following action steps will allow those on the front lines of healthcare to focus on how the functionality provided through use of an adopted EHR can improve workflow and quality. By acting upon the following recommendations, your Department will clearly demonstrate the intent of the EHR Incentive Program: improving care by helping EPs understand and use EHRs appropriately.

**Proposed Solutions:**

1. Simplify and resolve issues with the registration and attestation processes.
2. Allow adequate time for EPs and EOs to attest for a particular year. We encourage CMS to allow at least a three-month post-reporting period to attest for a particular year to allow EPs or EOs sufficient time to calculate the Meaningful Use measures and the CQM summary report. We make this recommendation due to the complexity of generating this type of summary report - particularly for EPs that recently purchased and implemented a certified EHR.
3. Beyond 2011, we strongly encourage CMS to accept the summary information for quality measures electronically should providers want to submit in that format, as EHRs are capable of reporting in this manner.
4. Publish HHS's process for conducting Meaningful Use and Certification compliance audits, including:
  - a. Clarify how reliance on FAQs will be viewed from a compliance perspective, particularly given the fact that the HHS Office of Inspector General has included audits in its work plan;
  - b. Identify the type of documentation needed to demonstrate compliance in the event of an audit; and
  - c. Specify whether requirements in the final rule or clarifications from the FAQs are going to be enforced.
5. Establish a CMS appeals process for providers to resolve disputes on program eligibility, qualification for incentive payments, and payment calculations.

**Evaluate Regulatory Timeline**

We support and appreciate the Department's efforts to work collaboratively with a broad community of stakeholders to discuss these concerns. Such collaboration includes establishing a prioritized health transformation timeline that sets goals and priorities for healthcare improvement enabled through health IT, while balancing other mandates competing for similar resources like those required under HIPAA (e.g. 5010 and ICD-10). We envision the timeline as the basis for implementing all transformation activities, including but not limited to incentives, processes, and technology improvements.

To allow adequate time for safe development, implementation, and adoption of software, the timeline for the next stage of Meaningful Use needs to be at least 18 months between final rules on Meaningful Use, Certification, and standards, and the start of the next stage of Meaningful Use, as recommended by the Health IT Policy Committee. Given the context of the health IT changes in ARRA, ACA, and ICD-10, sufficient time for Meaningful Use Stage 2 is especially critical for EPs and EOs.

**Proposed Solutions:**

1. Publish official and immediate CMS guidance on the timeline for the start of Meaningful Use Stage 2 to enable planning and investments to take place, followed as soon as possible by publication of associated proposed and final regulations and Certification test methods.

2. Establish a process to prioritize Meaningful Use, ACA, HIPAA, and ICD-10 initiatives based on healthcare community input and use this input to inform the Meaningful Use Stage 2 proposed and final rules.
3. Include at least 18 months between the final rules on Meaningful Use, Certification, and standards and the start of the next stage of Meaningful Use.

In conclusion, we thank you for reaching out to us to seek our engagement and suggestions. We share your goal of increasing the engagement of EPs, EHS, and vendors, and are excited to provide our thoughts to you. Our collaborative group stands ready to work with your Department and its leaders to ensure our shared goals are realized and to work with you on these five key points. Our point of contact is Tom Leary, HIMSS Senior Director for Federal Affairs, who can be reached at 703-562-8814 or [tleary@himss.org](mailto:tleary@himss.org).

Sincerely,

AHA – American Hospital Association  
AMA – American Medical Association  
AMDIS – Association of Medical Directors of Information Systems  
CHIME – College of Health Information Management Executives  
EHRA – Electronic Health Record Association  
FAH – Federation of American Hospitals  
HIMSS – Healthcare Information and Management Systems Society

cc:

Donald M. Berwick, M.D., M.P.P, Administrator, Centers for Medicare and Medicaid Services  
Farzad Mostashari, MD, ScM, National Coordinator for Health IT

Attachment:

PowerPoint Presentation: “Certification for Meaningful Use -- Experiences and Observations from the Field, June 2011”