May 3, 2010

The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS-0033-P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Proposed Rule (Vol. 75, No. 8), January 13, 2010

Dear Secretary Sebelius:

We, the undersigned organizations, appreciate the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule on the Medicare and Medicaid electronic health record (EHR) incentive programs. We fully support the purpose of the *American Recovery and Reinvestment Act of 2009* (ARRA) to encourage the adoption and use of EHRs and infuse stimulus dollars into the health care sector. We want to ensure, however, that the provisions of the statute are implemented in a manner that will remove barriers to and promote the widespread adoption of health information technology (HIT).

As a coalition of groups from across the health care spectrum who have each submitted our specific comments about the rule, we share several common views on the proposed rule, including the need for:

- Greater flexibility in meeting meaningful use;
- More time to achieve meaningful use;
- Small physician practice representation on the Health IT Policy Committee;
- A feedback loop on program performance;
- A focus on clinical functions;
- A less restrictive definition of a hospital;
- Less burdensome reporting requirements;
- Greater attention to operational issues; and
- Harmonizing the Medicaid and Medicare EHR incentive programs.

GREATER FLEXIBILITY IN MEETING MEANINGFUL USE

Under the proposed rule, providers seeking to receive incentive payments must:

- Use a certified EHR system;
- Successfully implement all 23 (hospital) or 25 (eligible professional, or EP) objectives of meaningful use;
- Successfully report on up to 35 quality measures using the EHR (hospital); and
- Successfully report on HIT functionality measures.

The proposed rule takes an "all-or-nothing" approach, where failure to meet any one of the requirements means the provider will not receive an incentive payment. This approach does not acknowledge that providers have made enormous progress in creating and maintaining EHRs to improve patient care and safety. The inflexible sets of 23 and 25 requirements would result in very few providers being able to meet the all-or-nothing approach, despite having adopted numerous EHR components.

In addition, these requirements are asking for too much, too soon. They include advanced functions, such as computerized provider order entry, clinical decision support and electronic medication reconciliation, which generally occur at the end of a multi-year transition to EHRs. The proposed phase-in period for this aggressive set of requirements is unrealistic and fails to acknowledge that providers adopt EHR functions incrementally and are in different places in their adoption process. If finalized, it would likely result in even those providers with advanced HIT systems not meeting the requirement in fiscal year (FY) 2011. For physicians in small practices and rural providers, the unrealistic timeframes are even more problematic because they have further to go in their implementation of EHRs compared to larger providers.

Therefore, we urge CMS to require providers to implement a percentage or limited number of the meaningful use objectives and offer providers greater flexibility in choosing which requirements to implement.

The long-term goal of the program will remain for all providers to fully implement EHRs, but it is critical that individual providers be able to take a different path to reach that goal. Allowing for greater flexibility in meeting the definition of meaningful use will allow providers to best serve their patients and communities.

MORE TIME TO ACHIEVE MEANINGFUL USE

The ambitious goals of this program encompass many uses of technology and health information exchange infrastructure that are still developing, such as agreed-upon data standards, widespread health information exchanges, and the use of personal health records. Achieving these positive changes will take time. **Therefore, we urge CMS to extend the transition to meaningful use to 2017, consistent with the ARRA.**

Under the ARRA, providers can receive incentive payments through 2016. And, while the penalties for those who do not meet the meaningful use criteria begin in 2015, they are phased-in over three years, with the maximum penalty imposed in 2017.

This approach would provide a more realistic adoption curve without changing the payment and penalty schedule established in law.

SMALL PHYSICIAN PRACTICE REPRESENTATION ON HEALTH IT POLICY COMMITTEE

There is currently no member of the Health IT Policy Advisory Committee – the advisory body established under the ARRA to recommend a framework to the U.S. Department of Health and Human Services (HHS) for the development and adoption of a nationwide health information infrastructure – who represents small physician offices, despite the fact that small physician practices represent 80 percent of all outpatient office visits. **We recommend that immediate steps be taken to include representation from small physician practices in future meetings.**

NEED FOR A FEEDBACK LOOP ON PROGRAM PERFORMANCE

We also believe that it is critical that physicians receive feedback on their performance so they know if they are meeting the criteria for the incentive payments. We must avoid the pitfalls experienced with the Physician Quality Reporting Initiative (PQRI) program. We believe it is essential that CMS and the states establish a feedback mechanism so that EPs can be assured early on that the information they report on through attestation has been successfully submitted and received.

FOCUS ON CLINICAL OBJECTIVES

We urge CMS to drop the two proposed objectives/measures related to administrative systems: "check insurance eligibility electronically from public and private payers" and "submit claims electronically to public and private payers." These administrative activities are addressed under the HIPAA Administrative Procedures regulations and are overseen by CMS such that hospitals already face a financial penalty for submitting paper claims. These activities are undertaken through existing claims processing and practice management systems, which often share data with clinical EHR systems, but are rarely part of the EHR installation.

Including these objectives in the final rule would require that providers get their existing, functioning administrative systems certified through a yet-to-be-established federal process. This would add considerable expense and take IT staff away from implementing clinical EHR systems for no clear reason.

LESS RESTRICTIVE DEFINITION OF A HOSPITAL

The ARRA payment incentives are available to each hospital or Critical Access Hospital (CAH) that is a meaningful user of a certified electronic health record (EHR); ARRA defines a hospital as a Medicare subsection (d) hospital, which is a general, acute care, short-term hospital. CMS proposes to provide incentive payments to hospitals as distinguished by their Medicare provider number.

We are concerned about CMS's proposal to use Medicare provider numbers to distinguish hospitals for EHR incentive payment purposes. There is no standard approach to exactly which facilities a Medicare provider number encompasses and, in many hospitals, a single provider number can include multiple sites of a hospital system.

The cost of EHR implementation at each site far exceeds the purchase cost of the actual application or software. Each site is at least, in part, an autonomous unit, with specific systems and policies that must be independently reflected in an EHR implementation. For example, site installations must accommodate different network infrastructures of legacy systems, physician preferences, clinical protocols, expert rules systems, workflows and ancillary system integration. One site may be a children's hospital while another may be an adult acute care hospital, each requiring different interfaces and clinical systems. Further, hospitals incur additional administrative system costs for necessities such as workstation installation, servers and staff training, and differences in clinical services between sites may require additional unique variations between facilities.

Therefore, we recommend that, for purposes of the ARRA HIT incentives, CMS define a hospital as a discrete facility of service, so that individual sites of hospitals are eligible to separately qualify for the incentives. While CMS does not currently collect data by individual hospital site, it does have avenues through which it could do so, such as the cost report.

LESS BURDENSOME REPORTING REQUIREMENTS

As proposed by CMS, the EHR incentive programs would impose a tremendous reporting burden on providers that would take valuable financial and staff resources away from the use of EHRs in clinical care.

Many of the proposed HIT functionality measures would require 100 percent manual review of medical records to determine the denominator. This includes, for example, the share of orders placed through CPOE, the share of prescriptions done through e-prescribing, and the share of all laboratory reports entered into the EHR as structured data.

In addition to the HIT functionality measures, CMS has proposed a large number of quality measures that providers must submit using the EHR. However, many of these measures are not yet specified for electronic reporting, let alone built into vendor products that have been installed and tested for validity, reliability and feasibility of reporting.

Therefore, we recommend that CMS only require reporting of HIT functionality measures that can be generated directly from EHRs, with no need for manual chart reviews. We also recommend that CMS postpone the requirement on submission of quality metrics until there is evidence that the means to capture the data from EHRs and submit the data to CMS is validated. Testing of these processes should take place in the initial years.

GREATER ATTENTION TO OPERATIONAL ISSUES

The proposed rule contains limited information on how the EHR incentive programs will be operationalized. We appreciate the extreme time pressures on CMS to design the program but request that additional information be provided on operational concerns, such as the process to apply for meaningful use payments, the process to submit meaningful use data, and the specific information needed for attestation.

Given that this is a new and highly complex program, we also urge CMS to provide vigorous and well-planned contractor and provider education, so as to maximize the likelihood of success. To ensure successful implementation, CMS and its contractors also must give prompt feedback on missing or incomplete data in their attestations and other reporting, giving providers an opportunity to correct and re-submit their data.

Appeals process. In addition, we recommend that CMS implement for the Medicare program all of the appeals processes it proposes to require of state Medicaid programs. Specifically, to ensure that the program is implemented fairly, providers must have a process to appeal incentive payments, incentive payment amounts and provider eligibility determinations.

Retention Period. CMS proposes that eligible hospitals and professionals maintain evidence of qualification to receive incentive payments for 10 years after the date they register for the incentive program. However, a retention period of 10 years is unacceptable. Maintaining these records electronically for such a long period of time becomes costly since it requires additional storage as well as programming to catalogue and retrieve the information. There also will be technology changes that occur over 10 years, which could require the provider to convert stored data into new data retrieval media and then apply new security protections to safeguard this information.

Other regulations and laws requiring electronic retention of health records are significantly shorter than 10 years. For example, electronic retention for medical records is governed by state laws and is generally five years. **CMS should modify the retention period for evidence of qualification to receive incentive payments to five years, which is consistent with other retention requirements.**

HARMONIZING THE MEDICAID AND MEDICARE EHR INCENTIVE PROGRAMS

CMS suggests harmonizing the Medicaid and Medicare EHR incentive programs as much as possible, and we support CMS' efforts to develop one set of meaningful use criteria for both programs. Additionally, we urge CMS to prompt state Medicaid agencies to distribute Medicaid incentives in payment 2010 and 2011 – doing so will allow safety-net providers the resources to meet the meaningful use criteria.

We also urge you to allow CAHs to qualify for Medicaid EHR incentives. There are nearly 1,300 CAHs serving patients in rural and frontier areas across the country. Access to capital is

one of their most difficult challenges, and it is critical that these hospitals qualify for the additional Medicaid incentives.

We greatly appreciate the hard work of CMS in crafting the NPRM under tremendous time pressures. We look forward to working with you to ensure a successful implementation of the challenging program, and achieving an e-enabled health care system that supports high-quality care, care coordination, fully engaged patients and improved public health.

Sincerely,

AMDA – Dedicated to Long Term Care Medicine
American Academy of Dermatology Association
American Academy of Family Physicians
American Academy of Neurology Professional Association
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American College of Cardiology
American College of Chest Physicians
American College of Gastroenterology
American College of Osteopathic Surgeons
American College of Physicians
American College of Radiation Oncology
American College of Radiology
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Geriatrics Society
American Hospital Association
American Medical Association
American Organization of Nurse Executives
American Osteopathic Academy of Orthopedics
America Psychiatric Association
American Rhinologic Society
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society for Reproductive Medicine
American Society of Cataract and Refractive Surgery
American Society of Hematology
American Society of Nuclear Cardiology
American Society of Plastic Surgeons
American Urological Association

Association of American Medical Colleges
Catholic Health Association of the United States
College of Healthcare Information Management Executives
Congress of Neurological Surgeons
Federation of American Hospitals
Healthcare Leadership Council
Heart Rhythm Society
Infectious Diseases Society of America
Medical Group Management Association
National Association of Public Hospitals and Health Systems
National Rural Health Association
North American Spine Society
Premier, Inc.
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Hospital Medicine
Society of Nuclear Medicine
The Endocrine Society