

June 26, 2009

David Blumenthal, M.D., M.P.P.  
National Coordinator for Health Information Technology  
U.S. Department of Health and Human Services  
Office of the National Coordinator for Health Information Technology  
200 Independence Avenue, SW  
Suite 729D  
Washington, DC 20201

**Re: HIT Policy Committee Meaningful Use Comments**

Dear Dr. Blumenthal:

The American Recovery and Reinvestment Act (ARRA) authorizes the Centers for Medicare & Medicaid Services (CMS) to provide financial incentives for eligible physicians who meaningfully use electronic health records (EHRs). These incentive payments begin in 2011 for eligible Medicare physicians; physicians who have not demonstrated they are a meaningful user of an EHR by 2015 will face reductions in their Medicare payments which start at 1 percent.

When implemented properly in a connected environment, widespread HIT adoption and use will transform the practice of medicine and provide physicians with a powerful tool by putting real-time, clinically relevant patient information and up-to-date clinical decision support tools in practitioners' hands at the point of care. ARRA enables the federal government, physicians, and others to work together to achieve the goal of widespread adoption and use of EHRs. It is important to note that the vision of a nationwide interoperable EHR environment cannot be fully realized without reforming our Medicare physician payment system and eliminating significant administrative waste from the health care system by simplifying and standardizing the current health care billing, payment and claims reconciliation process.

We the undersigned organizations, appreciate the HIT Policy Committee's efforts to promptly issue a proposal for meaningful use objectives and measures that must be met by eligible physicians to ensure receipt of the financial incentives specified in ARRA. In general, we support the Committee's objectives and vision as outlined in the proposed matrix released by your office. We are concerned, however, that the Committee's timeline to meet the proposed measures is too aggressive given that we continue to lack the necessary infrastructure, standards, and systems. We also have significant concerns with the following objectives and measures proposed by the Committee on: appropriate access to, exchange and reporting of health care data; costs associated with the dissemination of information; privacy measures including ineligibility for incentives due to an alleged HIPAA violation; and patient compliance with specified measures.

ARRA defines meaningful users of EHRs as eligible professionals who: use certified EHRs (which include e-prescribing functionality); engage in information exchange; and report quality measures. ARRA authorizes the Secretary of the Department of Health and Human Services (HHS) to make these requirements more stringent over time. Based upon a considerable amount of analysis and discussion, we are submitting a proposal for defining meaningful use of EHRs which includes: 1) guiding key principles that we believe are critical to achieving the goal of widespread adoption of EHRs and other health information technology (HIT), and to ensuring patient access to quality and timely care; and 2) an

achievable and predictable pathway toward meaningful use, including a set of program specifications for meeting the 2011 incentive payment timeframe and beyond. **Our proposal is aimed at ensuring that the “bar” is not set too high or too low; one that is reasonable and ensures that all eligible physicians in all size practices and specialties are able to take advantage of the incentives specified in ARRA.** Attached to this letter you will find our recommended principles and set of incentive program specifications.

Moving forward within a predictable pathway--and assigning years to those steps--is very much dependent on number of forces in play: the availability of the required EHR functionalities and standards; the readiness of several others in the health care spectrum to securely exchange data with physicians; physicians having real-time access to medical information and tools; and the ability of individual physicians to incorporate these technologies into their existing workflow. We strongly recommend a "check point" before moving from one level of meaningful user criteria to the next. This check point will help ensure not only physician readiness and the capacity of the system to meet these goals, but will also help assure continued access to safe, quality care for patients.

We appreciate the opportunity to comment on the Committee’s proposal and look forward to providing ongoing input to the Committee to ensure that the EHR meaningful use objectives and measures are reasonable and achievable for all eligible health professionals. Should you have questions about these comments, they can be directed to Mari Savickis at [mari.savickis@ama-assn.org](mailto:mari.savickis@ama-assn.org) or 202-789-7414.

Sincerely,

American Academy of Allergy, Asthma and Immunology  
American Academy of Dermatology Association  
American Academy of Facial Plastic and Reconstructive Surgery  
American Academy of Family Physicians  
American Academy of Home Care Physicians  
American Academy of Orthopaedic Surgeons  
American Academy of Otolaryngology– Head and Neck Surgery  
American Association of Clinical Endocrinologists  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American College of Allergy, Asthma and Immunology  
American College of Chest Physicians  
American College of Obstetricians and Gynecologists  
American College of Osteopathic Internists  
American College of Osteopathic Surgeons  
American College of Physicians  
American College of Radiation Oncology  
American College of Radiology  
American College of Surgeons  
American Gastroenterological Association  
American Geriatrics Society  
American Medical Association  
American Medical Directors Association  
American Osteopathic Academy of Orthopedics  
American Osteopathic Association  
American Psychiatric Association

American Society for Gastrointestinal Endoscopy  
American Society for Radiation Oncology  
American Society of Anesthesiologists  
American Society of Cataract and Refractive Surgery  
American Society of Clinical Oncology  
American Society of Hematology  
American Society of Plastic Surgeons  
American Urological Association  
College of American Pathologists  
Congress of Neurological Surgeons  
Heart Rhythm Society  
Infectious Diseases Society of America  
Joint Council of Allergy, Asthma and Immunology  
Medical Group Management Association  
North American Spine Society  
Society for Cardiovascular Angiography and Interventions  
Society for Vascular Surgery  
The Society of Thoracic Surgeons

Medical Association of the State of Alabama  
Alaska State Medical Association  
Arizona Medical Association  
Arkansas Medical Society  
Colorado Medical Society  
Connecticut State Medical Society  
Medical Society of Delaware  
Medical Society of the District of Columbia  
Hawaii Medical Association  
Idaho Medical Association  
Illinois State Medical Society  
Indiana State Medical Association  
Iowa Medical Society  
Kansas Medical Society  
Kentucky Medical Association  
Louisiana State Medical Society  
Maine Medical Association  
MedChi, The Maryland State Medical Society  
Massachusetts Medical Society  
Minnesota Medical Association  
Mississippi State Medical Association  
Missouri State Medical Association  
Montana Medical Association  
Nebraska Medical Association  
New Hampshire Medical Society  
Medical Society of New Jersey  
New Mexico Medical Society  
North Carolina Medical Society  
North Dakota Medical Association  
Ohio State Medical Association

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Oregon Medical Association  
Rhode Island Medical Society  
South Carolina Medical Association  
South Dakota State Medical Association  
Tennessee Medical Association  
Texas Medical Association  
Medical Society of Virginia  
Wyoming Medical Society

## RECOMMENDATIONS FOR DEFINING AND DEMONSTRATING MEANINGFUL USE OF CERTIFIED ELECTRONIC HEALTH RECORDS (EHRs)

### I. Guiding Principles for Ensuring Widespread Use of Certified EHRs

#### A. Timing of EHR Implementation

1. **Develop a Realistic, Scaleable, and Flexible Starting Point for EHR Adoption:** The definition of meaningful use should be realistic and scaleable to accommodate practices with varying IT adoption levels and with different capabilities. For example, the starting point must take into account the ability of a solo practitioner vs. a large group practice, a rural practice vs. an urban one, and specialties for which there are no certified EHR products available in the market today (e.g., oncologists, dermatologists, ophthalmologists, obstetricians). The definition should also incorporate flexibility so that practices can tailor their adoption plan in a progressive manner capable of expansion over a specified period of time.
2. **Allow Reasonable Time for Robust EHR Use:** It is important to factor in that for an average practice to move from initial adoption of an EHR system to more robust use will take at least 12-18 months.
3. **Incorporate Adequate Time for Finalizing Standards, Infrastructure, and Vendor Readiness:** Significant planning, training, software/system upgrades/replacements, as well as other investments for physicians, vendors, and other affected parties, must be incorporated as part of the implementation process and timeline. Unrealistic timelines must be avoided, especially if pre-conditions such as the availability of standards, infrastructure, and certified specialty-specific systems, and vendor readiness, have not been met. Attention should also be paid to learning from health information technology (HIT) demonstration projects and from other countries' experiences (i.e., United Kingdom) that faced significant challenges resulting from lack of infrastructure and preparedness.
4. **Ensure Adequate Technical Implementation Support:** Reengineering workflow takes time and extensive technical and implementation support will be critical to ensure overall success of incorporating new technologies into current practice workflows. Physicians will need substantial technical support to assist in the significant changes that accompany the incorporation of new technologies into practice workflow.
5. **Outreach and Communication:** An outreach plan must be developed and information on critical components such as the availability of technical support and requirements for demonstrating meaningful use and certification must be readily, regularly communicated to physicians and other health care partners well in advance of the 2011 incentive payment start date.
6. **Factor in the Implementation of Version 5010, ICD-10, and Other Related Compliance Deadlines:** The health care industry, including physicians, will be migrating to the next version of HIPAA electronic transactions standards,

Version 5010, by January 1, 2012. Moreover, the transition from using ICD-9 to ICD-10 codes must occur by October 1, 2013 which is expected to be an even more complex undertaking than the adoption of the first version of HIPAA standards (4010) and the transition to use of the National Provider Identifier (NPI). The implementation timeframe must factor in vendor, physician, and other health care partner readiness for all of these significant transitions that will occur simultaneously with the incorporation of HHS' recommended standards for qualifying EHRs.

## **B. Access to and Use of Health Information Technologies**

1. **Choice of Technology that Best Supports Workflow:** Physicians should be permitted to select the technology of their choice (i.e., registry, EHR, e-prescribing, mobile technology) that best meets their practice needs and workflow in order meet the definition of meaningful user. This will afford the greatest flexibility for physicians and presents a more inclusive approach for participation while furthering the intended goal of improving patient safety and coordination of care. Attention should be placed on how the technology can be incorporated into existing workflows to improve the delivery of health care services at the point of care. For example, the technology needs of a traditional office-based physician practice could vary from those who practice remotely and/or do not practice in a traditional office-based setting (e.g., physicians who treat patients in their homes need to use mobile technology).
2. **Access to Patient Information When and Where Physicians Need Information:** Facilitating care coordination, improved quality of care, and greater health care efficiency will require that all physicians, including those who typically have direct or indirect contact with the patient, have access to a patient's information when and where they need it. For example, all physicians including hospital-based physicians (i.e., anesthesiologists, pathologists) who are not eligible for incentives under ARRA, must have full access to patient records across settings of care to ensure that all patients receive the appropriate and necessary care, at the right time, based on access to a comprehensive patient history.

## **C. Demonstrating Meaningful Use**

1. **Tailor Meaningful Use Criteria Appropriately:** The definition of meaningful use must accommodate physicians who do not engage in all the core functionalities of e-prescribing, exchanging information for the purpose of care coordination, or reporting clinical measures, as described in ARRA (e.g., low-volume prescribers, physician who do not issue prescriptions to his/her patients or physicians who do not review and/or exchange certain health data). It must also accommodate physicians who are low prescribers of non-controlled substances.
2. **Account for Situations Beyond a Physician's Control:** There must be mechanisms built into the process for demonstrating meaningful use that account for situations that make it exceptionally difficult or impossible for a

physician to comply with the criteria outlined in the below table. Some physicians may not have an adequate number of quality measures available for reporting for their specialty or subspecialty and other physicians may practice in areas with limited information exchange. In addition, others may experience significant practice interruptions due to unforeseen circumstances like natural disasters.

3. **Establish Multiple Reporting Mechanisms:** There should be multiple methods available for physicians to report that would accommodate individual practitioner's needs and circumstances. The methods by which physicians "demonstrate" they are a "meaningful user" of an EHR should be as reasonable as possible without creating undue hardships on physicians, and the reporting capability should be available online. The determination of methods for demonstrating meaningful use must include physician input.
4. **Allow Flexibility in Demonstrating Meaningful Use Over Time:** The requirements for demonstrating meaningful use should evolve over time from basic to more complex requirements. Proof of meaningful use should not be overly burdensome to produce. We recognize that the reporting mechanism will change over time as the level of usage changes and mechanisms such as automated built-in reporting may become more prevalent.
5. **Clearly Define Eligibility Criteria:** The criteria for qualifying for financial incentives must be well-communicated and easily understood by physicians.
6. **Inclusive Definition for Certain Hospital-based Eligible Professionals:** Many physicians who furnish substantially all of their services in the hospital setting also maintain office-based practices outside the hospital. Hospital-based eligible professionals, who also provide a substantial amount of services within their office-based practices, should be eligible for incentive payments for adoption and use of qualifying EHRs in their office-based practices.

#### **D. Certification of Products and Product Functionalities**

1. **Establish Flexible Certification Requirements:** For the purposes of ARRA incentives, unless there is a process in place that can accommodate the influx of EHR products, physicians who are using: a) CCHIT-certified products; b) products that are in the formal process of being certified by CCHIT but are not yet certified; c) other systems like "homegrown" EHRs; and d) systems that meet the criteria named in Phase I in the table below, should be considered "certified" for 2011. Moving beyond 2011, a variety of certified products will be needed in order to accommodate the information needs and practice workflows of different specialties.
2. **Need Key Product Functionalities:** Key product functionalities are needed in the long run to ensure optimal meaningful use of technology:
  - a. **Usability:** The usability of EHRs and other technologies will directly impact a physician's ability to deliver high quality care efficiently. Products must support decision-making and physician workflow, enhance processes that improve health outcomes, and reduce unnecessary costs.

- b. **Patient Privacy Protections:** Patient's personal health information is protected and secure and available only to appropriate individuals and entities;
- c. **Standard Clinical Terminology:** Standard clinical dictionary of data elements by specialty or condition – for all specialties or clinical conditions, a set of structured data elements based on the clinical evidence must be defined and specified for integration into products for quality measurement and clinical decision support purposes (e.g., for cardiologists, ejection fraction values should be captured in discrete data fields and there should be standardized coding for these data);
- d. **Interoperability of Systems that Provides Secure and Seamless Data Exchange:** Bi-directional electronic exchange between a physician's system and an external entity(s) is necessary to facilitate the secure access to and exchange of important patient health information (e.g., laboratory reports, radiology reports, medication history);
- e. **Incorporation of Quality Measures:** Integration of a standardized set of quality measures - quality measure developers, such as the AMA-convened Physician Consortium for Performance Improvement® (PCPI) continue to work with all specialty societies to define the necessary data elements and quality measures that should be integrated into EHRs and work in concert with those who develop clinical decision support applications. This standardized set of measures should be aligned with the current and planned initiatives of other federal agencies;
- f. **Clinical Decision Support:** Clinical decision support that reasonably enhances decision making skills of EHR users within a clinical workflow (e.g., drug-drug alerts, drug-dose support, clinical reminders, evidence-based order sets, medication reconciliation, real-time access to a patient's entire medical record during any encounter, and remote access to a summary of critical data);
- g. **Querying and Reporting Capabilities:** Querying and reporting functions are available at the point of care that enable physicians to calculate baseline and continuous metrics both for each patient and in aggregate including reports on:
  - patient visits (e.g., to monitor follow-up, return visits);
  - patient populations by condition or procedure as defined by the practice (i.e., patient registry);
  - performance on quality measures that can be tracked over time; and
- h. **Common Format for Data Capture:** Functionality for capturing and exporting data using a common format that allows physicians to send the same data to multiple external organizations.

## **II. Charting a Pathway Towards Meaningful Use of Certified EHRs**

The requirements for becoming a meaningful user must be reasonable and achievable for physicians. Below is a proposed set of specifications to demonstrate meaningful use of an EHR system. This proposed set is tied directly to the elements specified in ARRA that describe meaningful use – electronic prescribing, information exchange, and quality measurement.

These specifications should be tailored for a given practice and/or specialty. Not all of the specifications may be relevant to a physician in which case the physician could demonstrate meaningful use of EHR technology through the remaining pertinent specifications. To provide context for how these specifications would be operationalized, an example focused on the treatment of congestive heart failure is also included.

Before we outline the specifications in the table below, it is critical to note that the ability for physicians to meet them is contingent upon a number of key assumptions. Unless the below mentioned assumptions are met, the end goal of to improving health care quality and efficiency through widespread adoption and use will not be fully realized.

**These key assumptions are:**

- **Specifications for 2011 should be no greater than what is listed in the table below.**
- **The timing of the specifications outlined in Phases 2-5 and beyond must be determined carefully factoring in the following critical interrelated pieces:**
  - **The interoperability standards have been developed, adopted, tested, and working successfully in readily available and affordable products for all applicable specialties;**
  - **Updates to coding terminologies (e.g., transition from ICD-9 CM to ICD-10 CM) are readily available with uniform mapping standardization across external entities that can be seamlessly integrated into each EHR;**
  - **Health care partners are capable of exchanging the requisite data and that data is presented in a way that is understandable to the physician (i.e., a pharmacy benefit manager (PBM) is capable of sharing complete medication history with physicians for their patients and formulary data shared by PBMs can be accepted by EHRs to help physicians select appropriate drug);**
  - **The national, regional, and local infrastructures have been substantially developed to allow for the electronic, secure exchange of patient health information;**

- The Secretary of HHS has defined the requirements for incentive payments through the rule making process; and
- There is continued input of physicians on the timing of the suggested specifications prior to any adoption requirements.

**Program Specifications Toward Defining a Predictable Pathway Predicated upon above Key Assumptions:**

<b>Timeframe</b> NOTE: In order to move from one phase of the pathway to the next, the specifications must be incorporated and available in at least 90% of EHRs in the market.	<b>Electronic Prescribing</b>	<b>Information Exchange for Care Coordination</b>	<b>Quality Measurement</b>	<b>EXAMPLE – Congestive Heart Failure</b> (Quality Measures based on evidence and utilizing data elements defined in available guidelines)
Phase I (2011)	(a) Use of drug interaction alerts at the point of prescribing  (b) Transmission of at least 25% eligible prescriptions electronically (i.e., exceptions for controlled substances, situations when patient does not want prescription sent electronically, pharmacy can not except electronic prescriptions)	(c) Electronic exchange between physician and pharmacy (assumes that pharmacies have electronic prescribing capability)  (d) Record primary language, race, and ethnicity  (e) Send reminders to patients for preventive/follow-up care	(f) Take steps toward developing a patient registry and capabilities to incorporate quality measurement to the extent they are available for a particular specialty  (g) Ability to capture medication list, problem list, and allergies as structured data elements (dependent upon standard practice for a specialty)  (e) Begin to capture data elements in standard code terminologies (e.g., CPT <sup>®</sup> Category I, NDC, RxNorm codes, ICD-9 CM codes)	Begin to confirm denominator requirements for all HF Quality Measures at a minimum: <i>office visits</i> <i>diagnoses</i>  Begin to confirm numerator requirements for HF Quality Measures: <i>medications</i>  Begin to track medical and patient exceptions that will drive QI focus; analysis of variations; patient shared decision making: <i>allergies</i>

Phase 2	<p>(a) Access to patient medication history</p> <p>(b) Transmission of at least 50% eligible prescriptions electronically (i.e., exceptions for controlled substances, situations when patient does not want prescription sent electronically, pharmacy can not except electronic prescriptions)</p>	(c) Electronic receipt of laboratory reports and radiology images ordered by the practice (e.g. scanned images and associated documents)	<p>(d) Add required data elements for quality measurement and begin to utilize query and internal reporting functions</p> <p>(e) Query records for patients with a specific condition or procedure</p> <p>(f) Identify a patient population for monitoring and determine baseline metrics (i.e., establish patient registry function) for targeting of specific conditions and for reduction of health care disparities</p> <p>(g) Expanded set of data elements in standard code terminologies (e.g., CPT® Category II, SNOMED)</p>	<p>Produce and review registry of patients with heart failure.</p> <p>Confirm additional denominator requirements: <i>Left Ventricular Ejection Fraction (LVEF)</i></p> <p>Confirm additional numerator requirements: <i>Current medication list with start and stop dates</i></p> <p>Confirm additional patient exceptions: <i>clinical contraindication, drug intolerance, patient preferences</i></p>
Phase 3	<p>(a) Access to patient-specific formulary data at the point of prescribing</p> <p>(b) Transmission of up to 80% of eligible prescriptions electronically (i.e. exceptions for controlled substances, situations when patient</p>	(c) Receipt of electronic laboratory and radiology reports as structured data elements	<p>(d) Use active clinical decision support based on clinical guidelines and best practices</p> <p>(e) Identify at least three quality measures to track</p> <p>(f) Produce and review internal quality report</p>	<p>Based on the current capabilities, select three HF measures from among those prioritized for EHR implementation. Potential list of measures endorsed by NQF that could be prioritized: <i>Beta-blocker therapy</i> <i>ACE Inhibitor/ARB therapy</i> <i>Warfarin Therapy for Patients with Atrial Fibrillation</i> <i>Left Ventricular Functional (LVF) Assessment</i></p>

	does not want prescription sent electronically, pharmacy can not except electronic prescriptions)			Produce and review internal quality report on these quality measures
Phase 4	(a) Access to list of patients and prescriptions not dispensed by a pharmacy (i.e., access to fill status)	(b) Ability to electronically produce and transmit a patient summary to other clinicians  (c) Ability to transmit quality data to external groups	(d) Continued calculation of at least three quality measures as previously identified  (e) Comparison of results to practice's baseline metrics  (f) Test of data export capabilities	Compare performance internally against previous years  Assess data integrity; verify results  Test data export capability for 3 HF Quality Measures  Enables practices to identify areas for review and improvement; focus QI efforts
Phase 5		(a) Review a patient's past imaging history and past diagnostic images prior to ordering a diagnostic imaging exam to avoid duplicative procedures.	(b) Send quality measure data to external organizations	Data for 3 selected HF Quality Measures routinely queried and exported from the EHRs  Enables practices to demonstrate performance and quality of care provided  Enables population-wide analysis by external organization, particularly for variations in care

<p>Post Phase 5 Expected Outcomes</p>	<p>(1) More accurate prescription of drug and dosaging by removing problems with legibility of paper prescriptions (2) reduction in duplicate drug therapies prescribed (3) better adherence to drug therapies</p>	<p>(4) reduction in duplicate tests</p>	<p>(5) demonstrate proactive population management  (6) compliance with clinical guidelines  (7) focused QI efforts  (8) capabilities to incorporate next generation quality measures</p>	<p>Potential future HF Quality Measures in development:</p> <p>Outcome measure on functional status</p> <p>Optimal medical therapy</p> <p>Overuse of echocardiography</p> <p>Enables practices to begin to assess efficiencies in the practice</p>
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