ACP
American College of Physicians
Internal Medicine | Doctors for Adults

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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 Ave, SW
Suite 729D
Washington, DC 20201

Re: HIT Policy Committee Meaningful Use Comments

Dear Dr. Blumenthal:

The American College of Physicians (ACP), representing over 128,000 internal medicine physicians and medical students, is pleased to have this opportunity to discuss the definition of "Meaningful EHR Use" with the Meaningful Use Workgroup of the HIT Policy Committee.

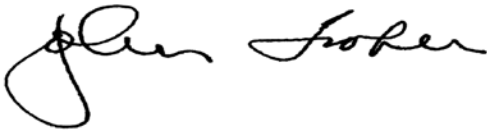
Health IT offers the opportunity to improve healthcare delivery, but only if it is coupled with major changes in other areas such as care delivery, reimbursement, and acceptance of new responsibilities by all stakeholders including clinicians, payers, employers and patients. The process to define meaningful use presents a rare opportunity for us to encourage fundamental changes to our healthcare system and focus on the important changes that are attainable through widespread implementation of health information technology.

Many stakeholder groups are proposing that the definition of meaningful use must include new functions as essential parts of EHR systems. While much of what is being proposed is potentially achievable over time, there are significant impediments to the adoption and implementation of many of these ideas given the aggressive timeline imposed by the HITECH Act. We are concerned that a rush to implement new technologies and new measures will result in unintended consequences ranging from failure of practices to achieve meaningful use to data processing errors that jeopardize patient safety.

ACP has a number of specific concerns and suggestions regarding EHR certification and the definition of meaningful use, which we detail in the attached document. In addition, we explore the complexity involved in measuring meaningful use with just one of the proposed clinical measures. In general, we support the proposed 2011 objectives that relate to the capture and use of structured, clinically relevant data. However we regard many of the proposed measures as tangential; representing diversions from the primary 2011 goal of data capture.

We appreciate the opportunity to comment on the Committee's proposed definition of meaningful use, and we and look forward to providing ongoing input to the HIT Policy and Standards Committees to ensure that the our shared objectives for health care reform through health IT are achievable, especially for small primary care practices. Should you have questions about these comments, please contact Thomson Kuhn at tkuhn@acponline.org or 202-261-4550.

Sincerely,



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Executive Vice President & CEO

THE AMERICAN COLLEGE OF PHYSICIANS

TO THE HIT POLICY COMMITTEE

MEANINGFUL USE WORKGROUP

Meaningful Use from the Practice Perspective

June 26, 2009

ACP has a number of specific suggestions and concerns regarding the EHR certification and the definition of meaningful use. These points fall into four broad categories:
1) Limitation of Time, 2) Certification Requirements, 3) Functionality in Practice, and
4) Measurement of Meaningful Use.

Limitation of Time

In order for physicians to receive the maximum incentive payment, they must be ready to demonstrate meaningful use by the end of 2011. Unfortunately, this deadline does not provide enough time for new initiatives (such as automated reporting to public health entities), new processes (such as reporting that requires data that is not collected), or significant additions to functionality as suggested by others. Meaningful use has to be defined in a way that allows medical practices to meet these requirements with reasonable effort. We are concerned that any attempt to add requirements that are not already validated in practice and currently available in CCHIT-certified systems will result in the inability of physicians to find and implement certified EHRs in order to demonstrate meaningful use by 2011. Further, we are concerned that rushing to develop and add new processes, measures, and functionality may come at the expense of necessary testing and validation to assure the accuracy and safety of these new EHR features.

Certification Requirements

Adding new, or more complex, requirements to EHR systems in order to achieve particular meaningful use runs the risk of raising significant barriers to EHR adoption. While these functions may be technically possible, they may not be feasible for most practices and hospitals due the additional work required and/or the implication of new or modified processes. We should not promote these new functions without extensive study and input from practicing physicians, office administrators, and other affected stakeholders.

Certification criteria must be based on existing HITSP specifications and CCHIT requirements. Adding new specifications and new requirements now will result in an insufficient number of EHR systems available for physicians to choose from and implement in time to meet the 2011 deadline. Vendor development cycle times are typically about 18 months. Pushing them to add functionality faster to meet ARRA deadlines could introduce usability and safety risks.

The certification requirements for 2011 must encourage widespread adoption of health information technology that incorporates sufficient functionality now and lays the groundwork to assure that more robust levels of meaningful use can be achieved over time. ACP recommends that EHR certification standards and requirements for demonstration of meaningful use can and

should increase over time. The HIT Policy Committee should create a feasible plan (that is, a six to 10 year pathway) for achieving many of the functions currently being proposed by some for 2011, such as efficiency and safety measures for which we have insufficient data to support the recommended changes to care provision.

Functionality in Practice

Clinical relevance, especially with a focus on patient-centered care, must be the primary criterion for choosing to implement and use EHR functions. There are several factors to consider before requiring new EHR functions such as: a) usability in actual practice; b) the cost to build and implement the feature versus its potential value; and c) the inefficiency and safety risks created when software is added without adequate integration into existing standard care processes. More important to this program is how the use of the function will be demonstrated without adding burdensome requirements to physicians already frustrated with imposed administrative and reporting requirements. Therefore, new features and/or functions proposed in the context of fostering meaningful use should not be fast-tracked unless they are: a) patient-focused; b) immediately usable in practice; c) add efficiency; d) do not create safety or security risks, and e) hold the promise of bringing more value than their development cost.

Certified health IT must be safe, secure, protective of patient privacy, and supportive of all relevant legal requirements for proper records management. In addition, all the health IT needs of a medical practice must be served by certified technology, not just requirements that are directly related to the definition of meaningful use. An EHR system that meets all of the meaningful use requirements but fails to provide the fundamental features every practice needs (such as maintaining a patient problem list, or linking to billing records) will be rejected by physicians and other clinicians in practice.

With regard to health information exchange (HIE), exchanges must ensure that common security functions are properly implemented. If data exchange is involved, the exchange partners must be willing and able to participate fully. We are concerned that some proposed exchange partners, such as state public health agencies, will not be able to manage their end of any data exchanges, leaving many practices without a feasible exchange partner. In such cases, evidence of the readiness of a provider to perform the exchange should be considered sufficient to meet the requirements of the exchange measure.

Measurement of Meaningful Use

We agree with the Meaningful Use Workgroup that the initial goal must be to ensure that providers become regular and appropriate users of core EHR functionality. Unless this behavior is institutionalized in practices, there will be little hope of achieving broader objectives. The key to appropriate use is the routine capture of relevant clinical data in structured formats at the point of care. All of the proposed benefits of health IT flow from this activity. We cannot begin data collection for quality measures or any other purpose until providers have accumulated sufficient structured data. The most important goal for 2011 is that most (about 85%) of American clinicians should be using basic EHR (health IT) functions. This is essential for addressing increasingly complex and effective use of health IT to transform healthcare.

We also agree with many of the 2011 objectives proposed by the Meaningful Use Workgroup. These objectives (such as maintaining a problem list) relate directly to the initial goal of structured data capture. We do not feel that all of the objectives fit this goal however. For

example, electronic ordering of anything other than prescriptions requires capabilities which do not routinely exist in the current ambulatory practice environment.

Our primary concern with the Meaningful Use Matrix is that there is a disconnect between some reasonable and appropriate proposed objectives and many of the proposed measures for 2011. It is difficult to envision how these proposed measures of "meaningful use" can be defined, promulgated, implemented, and measured by 2011 other than via data that practices currently create and can submit from their EHRs, including transmissions to pharmacies. We understand that, for CMS to pay for reporting of a measure in 2011, the measure must be in use by CMS in 2010. While meaningful use should ultimately include important activities such as metrics for care coordination, referral/test tracking, and transitions in care, it is not feasible to design and validate these metrics for use in 2011. ACP recommends that these important measures of meaningful use be deferred for now but included in the proposed six to 10 year pathway.

ACP recommends starting a consensus-building process regarding the definition of meaningful use and that this definition should be:

- Linguistically clear
- Concise
- Evidence-based
- Valid and reliable over time
- Least burdensome and disruptive measurement option available
- Operationally defined (An operational definition identifies one or more specific observable conditions or events and then specifies how to measure that event.)
- Measurable with currently available measures
- Visibly linked to care quality (including safety) and efficiency (i.e. having face validity)
- Practical for small practices and hospitals
- Specifically, not dependent on the cooperation of information-exchange partners
- Protective of patient privacy

To measure meaningful use of health IT as intended by the legislation, it may seem expedient to select existing quality measures and existing measurement systems, such as PQRI, not because they are appropriate, but because they are available. While we support the move to EHR-based reporting as opposed to reporting solely based on claims, we are concerned with how the data gets into the EHR so that it can be reported. For example, if a requirement is to report laboratory data from an EHR but those laboratory data must be manually entered into the EHR, a key factor influencing the performance for this measure would simply be the ability to type. Is this a demonstration of meaningful use of health IT?

Reporting requirements must be flexible to fit the inherent differences among practice types, medical specialties, and care settings. For example, rural and safety-net providers may still have challenges with internet connectivity and not all practices manage Type 2 diabetics. Also, there should be multiple pathways for reporting, such as through intermediaries, to account for variations in practice capabilities and existing processes.

Possible targets for measuring meaningful use include:

- Reconciled problem lists;
- Reconciled medication lists;
- Allergy information updated at least annually;

- Prescriptions e-prescribed when appropriate and permitted;
- Lab and imaging results received electronically;

ACP supports e-health activities that enhance patient-physician collaboration and believes that all of these data (including test results, not just orders) should be available to the patients.

Analysis of a Proposed Measure

The following are some of the challenges we anticipate to adopt/adapt one of the most common clinical measures being proposed as a metric for meaningful use: "% diabetics with A1c under control [OP]?" Some of the issues listed below may be addressed by ongoing work, but at this point, these are existing concerns that will require definitions, consensus, measurement development, testing and validation:

- There is not agreement among experts on a definition of "under control." It is generally agreed that different patient populations should have different A1c target levels. How should these different populations be identified and what should the specific target for A1c be? How recent must the lab result be? Should it be the average of several labs results, or just the latest one?
- There is no agreement on what inclusion criteria should qualify a patient as a "diabetic." Is this an entry found in a problem list, an ICD-9/ICD-10 visit code, use of certain drugs, or is this based on a certain value for one of several possible lab tests?
- What is a "patient" in the context of this measure? How much time can elapse since the last visit for a patient to still be considered active?
- What conditions might a patient have that would make the patient inappropriate for this measure? Where do patient preferences enter in? How do we take into account severe co-morbidities?
- There is no agreed upon measure for reporting on a population. All current PQRI reporting, for example, is based on individual encounter reports. This method would preclude registry-based reporting and current EHR-based reporting pilots. How is a "population" defined? By physician? By practice? If a patient is seen by more than one physician, is he/she included in all "populations" or if not, how is the appropriate attribution made?
- There are no approved methods for reporting a population A1c measure.
- There is no technical standard for a population-based report.
- There is no standard for specifying the components of the measure, such as the appropriate data fields where exclusion data will be found.
- No existing quality measures provide ICD-10 code values, yet ICD-10 will be required before the end of life for the 2011 measures.
- The capability to report each measure will require significant programming by vendors and consultants. Is it assumed that the purchasers of these systems will cover the entire cost?
- CMS has no existing capability to accept and manage population-level data.
- Most measures require manual effort to compile. Each measure imposed will result in increased costs and time to providers.
- This measure could be just as easily reported without an EHR system. Measures of meaningful use should leverage the effective use of an EHR system.
- For many physicians, there will be a tradeoff between the cost and time required to perform the reporting themselves vs. the cost and time required to have a third party, such

as a registry service, do it for them. Many physicians who tried and failed to report PQRI themselves will feel pressured to pay a third party to reduce the risk of complete failure.

Summary

In closing, ACP strongly supports the objectives of HITECH and the payment incentives offered to stimulate adoption of health information technology. However, we have significant concerns that in the effort to leap forward into a health IT-enabled environment, that some proposed definitions of meaningful use and the certification process for EHRs will add unrealistic requirements for reporting on measures for which the capabilities to report do not currently exist and which may therefore result in additional burdens to our already stressed health care system. We must take this opportunity to significantly stimulate health IT adoption/implementation and place the United States on a logical, evidence-based pathway towards technology-enhanced quality improvement, and resist the temptation to introduce untested standards or prematurely add requirements for well-intentioned but as yet undeveloped functions. At this critical time, we cannot afford to underestimate the challenge of complying with new requirements which could lead to the unintended consequence of delayed adoption of health IT – or worse, enormous pressure to rapidly adopt technology that fails to deliver on the promise of improving health and bending the curve on health care costs.