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June 25, 2009

Dear Dr. Blumenthal:

Thank you for providing the opportunity to comment on the draft recommendations for the definition of meaningful use of electronic health records (EHR) which CMS will incorporate into its incentive program for physicians and hospitals in the years 2011 to 2015.

As Secretary of the Executive Office of Health and Human Services for the Commonwealth of Massachusetts I serve as the chair of the Health Information Technology (HIT) Council the board of the e-Health Institute which oversees the statewide deployment of EHRs and health information exchange. The Council has reviewed the draft recommendations for meaningful use and I am attaching our comments and recommendations.

The Council supports the vision and "ultimate goal of meaningful use of an EHR to enable significant and measurable improvements in population health through a transformed health care delivery system." We agree that the National Quality Forum's "National Priorities and Goals" is a good starting framework for developing meaningful use measures. We recommend, however, that the Committee also consider other national priorities (e.g. Healthy People) to identify specific areas of clinical focus and identify national priorities.

We appreciate the tremendous effort made by the working group. Each of the five domains of meaningful use have clear goals with defined measures for each of the proposed components presented for each applicable year. This important document clearly outlines the working group's recommendations and facilitates the review and comment process.

The Council's comments and recommendations address the measures themselves, the timing of inclusion of measures in the incentive program, and the overall incentive program process.

We very much appreciate the opportunity to contribute to this important process.

Sincerely,

A handwritten signature in black ink, appearing to read "JudyAnn Bigby".

JudyAnn Bigby, M.D.

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Measures

The Council makes the following recommendations:

- Review a range of national priorities for health improvement and use these in the process of defining measures to track improvement in health.
- The timeline should reflect not only growing sophistication in use of HIT but also progress in addressing specific clinical conditions. For example, reporting BMI (in 2011) is not the desirable endpoint. We would want to see whether obesity rates decrease or the impact on diabetes. Include relevant follow-up measures for some indicators in 2013 and 2015.
- Develop a menu of clinical measures relevant to different clinical priorities depending on geographic locations, different patient populations, specialized care, and the need to respond to state health priorities. Solicit input from specialty societies to identify additional measures.
- Resist excessive dependence on defining meaningful use with process measures to reflect Advanced Clinical Processes. Requiring physicians to report on these types of measures could prove burdensome. Selecting a few measures for reporting may not reflect significant progress toward practice that leads to improved outcomes, different providers may be able to achieve the desired outcomes in different ways, and focusing measurement on a specific isolated process reinforces the practice of “teaching to the test.”
- Develop measures that show clear progress in the development of patient and family engagement in healthcare through HIT tools. Access must be timely, which should be defined and then measured from the start. Patients should also be able to access lab results and prescription information to allow for real-time care management at home. As soon as providers are required to have these parts of the record, patients should be given access. Develop measures to gauge patient use of on-line self-management and shared decision making. Measures should ensure a feedback loop between patient-generated information and provider.
- All measures must have clear and concise definitions. (e.g. high risk medications for the elderly and inappropriate use of imaging) All measure definitions will need to be agreed upon, consistently utilized, and measurable without excessive administrative burden.
- A mechanism for how each measure will be assessed should be defined and articulated when final definitions are published. For example, how will CMS assess the ability to exchange health information with external clinical entities in 2011? How will external clinical entities be defined? How will CMS know if an MRI is “not necessary?”

Timing of measure inclusion in the incentive program

Comments related to specific measures and their timelines are included at the end of this document. We recommend the following principles when considering a measure for inclusion in a given year’s incentive requirements.

- Narrow the gap between small independent physician offices and practices that are supported by organizations or systems. A schedule that is too aggressive will further widen the gap between large provider systems and small to medium sized physician offices. The former will have the

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resources to upgrade their existing HIT products and services. The small to medium sized physician office will find it difficult to implement or upgrade product without assistance.

- Coordinate the meaningful use incentive program with the support outlined in Chapter XIII of the ARRA. The vast majority of small to medium sized practices are waiting for loan and technical assistance programs to adopt an EHR, a process that will take more than a year to accomplish once the loans are available. These practices will not be able to meet aggressive measures in 2011.
- The technical infrastructure for any given measure to be operational in the incentive program must be in place no later than January of the preceding fiscal year. As an example, CMS does not currently have the capability to import EHR generated Quality Measures; many labs are not ready to report lab results compliant with HITSP standards, HIE exchange structures and processes (not funded by the ARRA until 2011) will be necessary to effectively exchange key clinical information among providers outside of an integrated delivery system, and many of the interoperability standards necessary for some of the information to be exchanged will not be in certified EHR products by early 2010.
- Establish appropriate administrative infrastructures to support success on meaningful use measures dependent on specific policies. HHS has not yet resolved the issue of e-prescribing for controlled-substances; payment mechanisms will be important for any services not currently reimbursed (i.e. secure messaging); and resolution of Clinical Laboratory Information Act issues must be resolved.
- Allow time for the delivery system to implement the workflow redesign necessary to incorporate advanced clinical processes. Many physicians will need technical support to effectively realize the benefits of the proposed components of meaningful use. It is still unclear what constitutes "best practice". While the Regional Extension Centers will likely be able to provide this technical assistance, it will still take time for the transition to occur, especially for new EHR users.
- All MU physician oriented measures must be in the realm of the physician's control, if they are to be tied to reimbursement and bonuses. Patient engagement is a critical component of improved health outcomes. It must be tied to certification and be part of the incentive scheme, meaning that vendors must be required to make these products accessible, usable, and useful to consumers, and consumer engagement should be a performance measure on which payers, vendors, and providers are evaluated and paid.
- All meaningful use physician oriented measures must be in the realm of the physician's control if they are to be tied to reimbursement and bonuses. Patient engagement is a critical component of improved health outcomes. However, one party making something available does not translate to action on another party's behalf.
- Avoid redundancy in reporting by delaying the requirement that physicians submit certain information until later in program when information shared can be more robust. Labs are currently required to report specific diseases to state public health departments. Until clinicians are comfortably using HIT for patient care purposes and all labs are reporting results directly to clinicians' EHRs, requiring physicians to also submit this information will be considered an added burden which will not improve the public's health. By 2015 EHRs will be able to report not only lab results, but other information relevant to public health as well.

Incentive Program

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We offer the following comments how CMS conducts the incentive program.

- Differentiating between hospital providers and physician providers is not sufficient. Those with EHRs in place for several years and those with the support of a large or integrated delivery system can meet aggressive timelines. Those waiting to adopt EHRs in 2010 cannot. Consider rewards based on a “point” system, with incentives offered for a lower number of points to those physicians just starting the process. This could also be applied to hospitals just undergoing electronic conversion in 2010. This would not change the final overall definitions, measures, or goals, but would support the disadvantaged providers in the delivery system as they “catch up.” Alternatively, providers could receive incentive payments based on the progress they have made toward meaningful use or you could use a separate timetable for those providers adopting in 2010.

Additional recommendations

- ONC should create a transparent and open process that analyzes technical readiness (interoperability standards, security and functionality) for all of the components of meaningful use before they are included in the incentive program. While some large organizations develop their own set of standards and specifications for HIT, until they are developed, tested, and available on a wide scale basis, all measures related to them should be postponed until later in the incentive program.
- The incentive program is specific to physicians and hospitals. There is a range of non-physician providers and non-hospital institutions that need to participate in “meaningful use”. Clearly define the range of providers who are expected to electronically receive information and develop a process for ensuring their engagement.

Specific recommendations for 2011 proposed measures

Improve quality, safety, efficiency and reduce racial disparities

- Incorporating lab results in EHR in coded format will require a tremendous amount of standardization. Labs will have the ability to e-report data to physicians. Delay the following requirements in the outpatient setting until 2013: calculating the % of labs incorporated into EHR, calculating the percentage of CPOE orders entered directly by a physician; and the reporting of quality measures requiring lab data.
- Require providers to collect race, ethnicity, and language data in a standardized manner.
- Develop organizational policies and procedures as well as metrics around maintaining problem and medication lists and using information, content management, ownership of the “lists,” authorization for updating and the role of patient in editing the lists.

Engage patients and families

- The appropriate measure for patient access to information in 2011 is whether or not this information can be accessed electronically. It is unrealistic to expect that by 2011 patients will have access to electronic copies or to electronic access to their records. In 2011 the first measure could be having a “patient portal” into an EHR or a secure messaging mechanism that allows communication about key pieces of data.

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- There are many patient education resources already available electronically. Providers should not have to replicate this function and reporting the percent that have access to educational resources would be very burdensome.
- Clinical summaries are not necessary for every patient encounter. Rather than report the percent of encounters for which clinical summaries were provided, assess the ability to fulfill this function.
- We strongly recommend that the implementation date for both inpatient and outpatient CPOE remain at 2011 since it offers one of the most beneficial capabilities.

Improve care coordination

- Requiring reports about medicine reconciliation is cumbersome and is only one of many process measures required for care coordination.
- We support the use of the Clinical Document (CDA) for sharing clinical summaries, the Continuity of Care Document (CCD).

Improve population and public health

- We recommend moving these measures to 2013, since infrastructure will not be in place by early 2010.

Ensure adequate privacy and security protections

- Proposed objectives not only include compliance with HIPAA which are currently in place but also include the Nationwide Privacy and Security Framework for electronic Exchange for PHI. The latter will take time since most of this work seems to be written to address the use of the health information exchanges. Since there are few operational exchanges in place today, the timeline for compliance seems too aggressive and we suggest delaying.
- Privacy and security are different with respect to degree of subjective versus objective measure. There are many complaints and accusations related to privacy violations that are not confirmed. An entity “under investigation” should not be penalized until the investigation has determined a violation actually occurred.

Specific recommendations for 2013 and 2015 proposed measures

2013

- Documenting family medical history is a standard that is widely accepted and required. There is no advantage to including it in the definition of meaningful use.
- Which home monitoring devices are included in the requirement to upload data? What assumptions did the working group make about the efficacy of home monitoring?
- One of the proposed metrics to “engage patients and families” states that providers must “provide patients with electronic copy of- or electronic access to- clinical information per patient preference.” The data source can be either an EHR or PHR which assumes that all providers will have an EHR in place by 2011 or patients will have access to their own PHRs. Providing clinical summaries for patients for each encounter will also be difficult to achieve. We recommend moving these measures to 2013.

2015

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- Self-management of chronic disease is an important component of chronic disease management. This measure should not be delayed until 2015.
- The accounting of disclosures rule will require additional staff to respond to patient requests, retrieve the information.

We recommend that you solicit public comment for measures for 2013 and 2015 after they are further developed.