David Blumenthal, MD, MPP National Coordinator for Health Information Technology U.S. Department of Health and Human Services 200 Independence Avenue, S.W. Washington, D.C. 20201

Dear Dr. Blumenthal:

The HIT Policy Committee (HITPC) appreciates the excellent work done by the Office of the National Coordinator (ONC) and the Centers for Medicare & Medicaid Services (CMS) in the recently published Notice of Proposed Rule Making (NPRM) regarding CMS's incentive program for the meaningful use (MU) of electronic health records (EHRs). In response to the NPRM, the members of the Meaningful Use Workgroup of the HITPC developed a set of comments, which were refined by discussion with the full Committee, and adopted by the HITPC. In the discussion below, we outline these recommendations and explain why we believe that these changes to the NPRM will result in more effective achievement of CMS's objectives with this incentive program for eligible professionals (EPs) and hospitals.

HIT POLICY COMMITTEE RECOMMENDATIONS:

RECOMMENDATION 1: REINSTATE HITPC RECOMMENDATION TO INCLUDE PROGRESS NOTE DOCUMENTATION FOR STAGE 1 MU DEFINITION FOR EPS.

The Committee strongly believes that electronic progress notes are a core element of EHR functionality. The Committee respectfully disagrees with the statements in the NPRM that electronic documentation of progress notes will naturally occur and is "not directly related to advanced processes of care or improvements in quality, safety, or efficiency." Electronic access to progress notes is key to delivering high quality care and for coordination of care for several reasons, including the following:

- Handwritten medical records not only take more time to decipher, their illegibility often obscures important information.
- Information that is not entered electronically at the point of care is lost forever, thus rendering the record less complete.
- Hybrid systems (part electronic, part paper) cause fragmentation of the record and inefficient workflow.
- Maintaining progress notes on paper impedes patients' access to this information because there is no structured way to provide patients with context to those data.
- Sharing electronic progress notes is fundamental to successful care coordination.

• Textual progress notes provide significant information about the patient that is not captured in the structured format elsewhere. Providers use these to know the patient as a human being, and patient focus groups suggest the best way to improve quality of care is for personal clinicians to "really know me."

Furthermore, the NPRM states that "documentation of progress notes is a medical-legal requirement and a component of basic EHR functionality," implying that eligible professionals are likely to enter electronic progress notes even without the objective and measure. Without an explicit requirement for including progress notes as part of the EHR, we are concerned that a significant portion of eligible professionals may choose to continue to document patient encounters on paper, which would significantly impede the goals of improving quality of care and care coordination. Furthermore, eliminating this requirement would obviate the need for vendor products to be certified to accommodate inclusion of progress notes.

Recommendation 1.0: Include "Document a progress note (clinician-authored note that documents what transpired during a patient encounter) for each encounter" as a Stage 1 MU criterion for EPs.

Recommendation 1.1: Signal clinical documentation as a required MU criterion in Stage 2 for hospitals.

Although the Committee believes that progress notes are equally valuable for inpatient care, it recognizes that the state of inpatient systems lags ambulatory systems in this regard.

RECOMMENDATION 2: REMOVE CORE MEASURES FROM STAGE 1.

Recommendation 2.0: Remove core measures from Stage 1 criteria

The concept of a set of core measures that should apply to all providers was originally proposed by the Policy Committee, but they were different from the ones proposed in the NPRM. The workgroup used the following criteria to assess candidates for core measures:

- Based on the Institute of Medicine's Six Aims (safety, timeliness, effectiveness, efficiency, equity, and patient-centeredness) and priorities identified by the National Priorities Partnership.
- Have an evidence-based link to improvement in outcomes.
- Can be measured using coded clinical data in an EHR (to minimize burden).
- Is captured as a byproduct of the care process (fits clinician workflow).
- Applies to virtually all eligible providers.
- Measures outcome, to the extent possible.

When reviewing the proposed core measures, the workgroup found that none of the proposed core measures adequately met the above criteria for inclusion. For example, NQF measures 0028 and 0013 are process measures, and the group felt that the outcomes-improvement goal of the overall HIT incentive program should be reflected in any measure to the greatest extent

possible. Measure 0022 suffers from a lack of consensus on definitions of "drugs to be avoided in the elderly" at this time, so the group felt it would be challenging to define this measure with enough precision that it could serve as a core measure. Consequently, the work group recommends removing the three proposed measures (NQF 0013, 0022, 0028) as "core measures" per se. The health priorities motivating the proposed core measures could be incorporated in relevant specialty measures in stage I, preferably using outcome-oriented measures.

The workgroup recognizes and supports the concept of having key national health priorities motivate selection of quality measures for the HIT incentive program. We will work with ONC to recommend strategies to identify key health priorities for which effective use of HIT has special applicability, and will re-explore the concept of "core measures" or "shared health priorities" for later stages.

RECOMMENDATION 3: REINSTATE HITPC RECOMMENDATION TO STRATIFY QUALITY REPORTS BY DISPARITY VARIABLES.

Recommendation 3.0: Providers should produce quality reports stratified by race, ethnicity, gender, primary language, and insurance type for internal use.

CMS has stated that an explicit health outcome policy priority is to "reduce health disparities." No assessment of disparity reduction can be made without stratifying data reports by these variables. The EPs and hospitals should attest that they make use of these stratified reports to assess the effectiveness of their efforts to reduce healthcare disparities.

RECOMMENDATION 4: PROVIDERS SHOULD MAINTAIN UP-TO-DATE LISTS OF PROBLEMS, MEDICATIONS, AND ALLERGIES

Recommendation 4.0: EPs and hospitals should report the percentage of patients with up-to-date problem lists, medication lists, and medication allergy lists.

In order to support quality of care and care coordination, key patient summary information (e.g., active problem lists, active medication lists, medication allergy lists) must be maintained in the electronic health record. The work group believes that one-time reporting on non-blank lists is a process measure that does not demonstrate meaningful use of EHRs. The work group proposes that the measure be an attestation that the problem lists, medication lists, and medication allergy lists are up-to-date. There are several approaches to assist providers in maintaining accurate lists, including comparative reports of encounter diagnoses, prescribed medications, and test results with diagnoses on the problem lists. The specific approach used by a provider organization would be left to the discretion of the provider. CMS audit could be conducted by chart review of a set of randomly selected charts.

RECOMMENDATION 5: REINSTATE HITPC RECOMMENDATION TO INCLUDE RECORDING OF ADVANCE DIRECTIVES FOR STAGE 1 MU DEFINITION FOR EPS AND HOSPITALS.

Recommendation 5.0: EPs and hospitals should record whether the patient has an advance directive as part of the Stage 1 MU criteria.

The Committee believes that, particularly for Medicare providers, recording of advance directives should apply to virtually all patients. In order to limit the application of the measure to an appropriate population, the measure could specify the percentage of all patients 65 and older who have an advance directive recorded.

RECOMMENDATION 6: REINSTATE BUT AMEND HITPC RECOMMENDATION TO INCLUDE PATIENT-SPECIFIC EDUCATION RESOURCES FOR STAGE 1 MU DEFINITION FOR EPS AND HOSPITALS.

Recommendation 6.1: EPs and hospitals should report on the percentage of patients for whom they use the EHR to suggest patient-specific education resources. Making available relevant educational resources is critical to the CMS stated health outcome priority to "engage patients and families" so that they can better understand their health condition and the meaning and importance of newly accessible data. In addition, providing patients and families with electronic access to their health information without guiding them to educational content to place that data into some context could overwhelm providers with questions about the meaning of that personal health information. The Committee members with experience of providing educational resources indicate that provider vetting of consumer educational content represents a substantial improvement in the content consumed by patients and families compared to unguided searching of the Internet. Several EHR vendors and health education content providers (including the National Library of Medicine's MedlinePlus) have developed partnerships that facilitate EHR-enabled connections to patient-specific content. We anticipate that relevant patient-education resources would be electronically available to patients. They may also be made available on paper, depending on how patients prefer to receive them.

RECOMMENDATION 7: REINSTATE HITPC RECOMMENDATION TO INCLUDE MEASURES OF EFFICIENCY FOR STAGE 1 MU DEFINITION FOR EPs AND HOSPITALS.

The Committee had recommended two high impact efficiency measures dealing with use of generic medications and coding of indications for high-cost imaging services. We note that neither of these measures was included, but no explanation was given. We note that the CBO discussion of benefits of using EHRs includes use of cost-effective generic medications. We recommend inclusion of measures that assess the meaningful use of EHRs to make cost-effective clinical decisions.

Recommendation 7.0: All EPs should report to CMS the percentage of all medications ordered through the EHR as a generic formulation, when generic options exist in the relevant drug class.

On page 1987 of the NPRM, CMS cites "prompt providers to prescribe cost-effective generic medications" as one of the key "Benefits to Society" in its impact analysis. In order for CMS to promote this benefit to society, the work group recommends reporting on this performance measure. We do not recommend setting a threshold in Stage 1.

Recommendation 7.1: CMS should explicitly require that at least one of the five clinical decision support rules address efficient diagnostic test ordering.

The NPRM states that EPs and hospitals need to: "implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering." In order to highlight an important area of health care system efficiency, the Committee recommends that the wording should be amended to: "implement five clinical decision support rules relevant to specialty or high clinical priority, at least one of which should be aimed at improving the efficiency of diagnostic testing or the ordering of appropriate treatment."

RECOMMENDATION 8: CMS SHOULD CREATE A GLIDEPATH FOR STAGE 2 AND STAGE 3 MU EXPECTATIONS

Recommendation 8.0: CMS should advance its timetable for the release of future MU NPRMs in order to allow adequate ramp-up time for vendors and providers.

To the extent possible, CMS should consider publishing the Stage 2 MU NPRM well before its anticipated December 2011 timeframe because vendors need more time to develop the appropriate functionality and providers need more time to integrate it into the clinical workflow. To the extent that such a timetable switch is infeasible, the Committee urges CMS to send strong directional signals through the Stage 1 MU final rule it issues this spring. Although the Committee recognizes that CMS cannot make Stage 2 and Stage 3 final recommendations without experience from the field on implementation of Stage 1 criteria, a strong signal of intentions would be very helpful to make the realization of future expectations more feasible.

RECOMMENDATION 9: CPOE SHOULD BE DONE BY THE AUTHORIZING PROVIDER.

In the description for calculating the numerator for the CPOE measure (p 1859 in NPRM), it states that the numerator is "orders issued by the EP entered using the CPOE functionality of certified EHR technology..." The Committee had intended that the numerator include only orders entered directly by the authorizing provider. The reason to emphasize direct entry of orders by the provider responsible for making decisions about the patient is because this maximizes the effect of clinical decision support offered through the EHR. At the same time, we recognize that in the normal practice of medicine, there are times when the authorizing provider is not able to enter orders directly (e.g., telephone orders, verbal orders in an emergent situation, academic medical center). Also, it was not our intent to circumvent state laws or to disrupt workflows that were designed to improve patient safety. For these reasons, the long-term target for orders that are directly entered by the authorizing provider will be lower than 100%.

Therefore, in future years, as the incentive-qualifying thresholds are increased, these considerations should be taken into account.

Recommendation 9.0: The numerator for the CPOE measure should define a qualifying CPOE order as one that is directly entered by the authorizing provider for the order.

RECOMMENDATION 10: AMEND PREVENTIVE/FOLLOW-UP REMINDERS CRITERION TO APPLY TO A BROADER POPULATION AND ALLOW FOR PROVIDER DISCRETION FOR WHERE TO FOCUS REMINDER EFFORT.

The intent of the original HITPC recommendation to provide reminders to patients was for the reminders to be patient-specific and to apply to all patients. The NPRM measure restricts the patient population to those over the age of 50 and does not look for patient specific reminders. The Committee recommends reinstating the patient specific reminders, and offers the following measure.

Recommendation 10.0: Change the measure to read, "For a chosen preventive health service or follow up reminder, report on the percent of patients who were eligible for that service who were reminded. The EP chooses the relevant preventive or follow up service for their specialty upon which to report."

The denominator would be: All patients who were potentially eligible (e.g., meet demographic criteria) and who had not already received the service. The numerator would be: All eligible patients who were reminded according to their preference (e.g., paper or electronic).

RECOMMENDATION 11: CLARIFY "TRANSITIONS OF CARE" and "RELEVANT ENCOUNTER"

Under the "Improve Care Coordination" category, the phrases "transition of care" and "relevant encounter" are not precisely defined. The Committee recommends deleting "relevant encounter" and using the following definitional approach to "transition of care" for the purpose of the meaningful use criteria: a "transition of care" occurs when a patient moves from one setting of care to another. For the purpose of the meaningful use criteria, a setting of care includes the following: hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility.

Recommendation 11.0: Delete "relevant encounter" from the medication reconciliation measure.

Recommendation 11.1: Define "transition of care" to be the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another.

RECOMMENDATION 12: ALLOW SOME FLEXIBILITY IN MEETING MEANINGFUL USE CRITERIA

We believe it is important to exhibit some flexibility in the "all-or-nothing" approach to earning meaningful use incentives, while preserving a floor of important mandatory functional use requirements. We wish to move the nation forward quickly towards meaningful use by applying the front-loaded meaningful use incentives, yet we recognize that providers and vendors must have sufficient time to achieve an extensive array of objectives and measures. Unfortunately is it difficult to predict which objectives and measures will be most difficult to achieve for a given provider in the local environment. Therefore, we believe that the incentive program should contain some inherent flexibility, and that it should recognize providers who make good progress toward Stage 1 meaningful use.

We recommend consideration of the following approach that gives eligible professionals and hospitals some flexibility in achieving the meaningful use objectives and measures. We propose that a provider (EP or hospital) organization be permitted to defer fulfillment of a small number of meaningful use criteria and still qualify for incentive payment. The deferment would last until Stage 2 criteria apply. To avoid allowing providers to skip an entire priority area (e.g., skip all of patient engagement), however, we suggest the following "3-0-1-1-0" proposal, which allows EPs & hospitals to qualify for Stage 1 MU incentives if they defer no more than the specified ("3-0-1-1-0") number of objectives in each category, as indicated in the table:

Recommendation 12.0: Eligible professionals and hospitals should be given the flexibility to defer up to 5 meaningful-use criteria as described in the table below, but must meet all mandatory objectives.

Priority area	# objectives that may be deferred by EP or hospital (all EPs and hospitals must fulfill "mandatory" objectives)	Mandatory objectives (all EPs and hospitals must meet these)
Improving quality, safety, efficiency, and reducing health disparities	3	 Have demographics recorded as structured data Use CPOE/Use of CPOE for orders (any type) directly entered by authorizing provider (for example, MD, DO, RN, PA, NP) EPs generate and transmit permissible prescriptions electronically (eRx)
Engage patients and families in their health care	0	
Improve care coordination*	1	

Improve population	1	
and public health*		
Ensure adequate	0	
privacy and security		
protections for		
personal health		
information		

^{*} The Committee voted 7-to-5 to defer one care coordination objective (versus no deferral), and 7-to-6 to defer one public health objective (versus no deferral).

RECOMMENDATION 13: REDUCE LEVEL OF QUALIFYING THRESHOLDS

In setting the qualification thresholds for the meaningful use incentives, the NPRM often used 80% or 50%. A number of issues have been raised by the public that point out several factors that may impede an organization's ability to achieve the thresholds, often beyond the control of the provider organization – either because of constraints in the local environment or limitations of the proposed measurement definitions. For example, in some rural areas of the country, the number of pharmacies capable of accepting electronic prescriptions may be less than 75%. In other areas, there may be legitimate local or workflow reasons why an organization may not be able to achieve high penetration for a function as described (see recommendation 9 comments). Also, some measures may be unduly burdensome to calculate because the component data may be available only through chart review or other manual counting methods.

Ideally, calculating a measure should be as automated as possible, using standardized, coded data. Where these data are not available in coded format, surrogate measures may be used to estimate the achievement of a meaningful use objective. By using a lower threshold and by adopting measures that use coded data from the EHR, we believe many of the objections to the thresholds proposed in the NPRM will be accommodated. At the same time, we believe lower thresholds would not deter organizations from achieving as much of the objective as possible. That is, it is unlikely that an organization would stop implementing or promoting effective use of a function just because it has passed the minimum threshold, as long as the threshold is not zero.

Therefore, the Committee recommends that CMS consider significantly lowering the higher qualifying thresholds listed in the NPRM (e.g., 75%, 80%) to a lower number that still represents a meaningful accomplishment (e.g., to 50% or 60%) towards the individual objectives.

The Policy Committee believes that thresholds may need to be tailored to individual objectives in the future. We will provide further recommendation on future thresholds based on feedback on the levels of achievement accomplished in the first year.

Recommendation 13.0: The qualifying thresholds for meaningful use criteria in stage one should be lowered significantly to a meaningful, non-zero level

Recommendation 13.1: Thresholds for future stages should be tailored for individual criteria based on program objectives and the overall performance of providers in year one, and should become more stringent over time.

RECOMMENDATION 14: USE "EHR-ENABLED" QUALITY MEASURES IN QUALITY REPORTING REQUIREMENTS

Currently, most quality measures rely on data from administrative and billing systems, even though these measures may not accurately reflect clinical quality. The meaningful use program provides an important opportunity to define quality measures that are based on clinical data stored in EHRs. By using coded clinical data in EHRs, not only do the measures more accurately reflect clinical performance, but the burden of calculating the measures is reduced.

The Committee recognizes that it may not be possible to develop new clinical quality measures specifically using coded data from an EHR (EHR-enabled quality measures) in the initial years, but we would encourage the department to select available measures that are defined using coded clinical data (e.g., measures that have been "retooled" by the National Quality Forum), and to commission additional measures to be developed for future stages in the program. This would ensure that meaningful measures are available not only for the HIT incentive program, but also to use in performance reports to monitor and continuously improve health outcomes – the ultimate goal of the HITECH Act.

Recommendation 14.0: Use quality measures that are defined using standardized clinical data captured in the EHR for the quality reporting requirements of meaningful use.

Recommendation 14.1: Support the development of "EHR-enabled" clinical quality measures that address national health priorities and are outcomes-oriented for use in future stages of the HIT incentive program.

The HIT Policy Committee sincerely appreciates the thoughtfulness that went into developing the NPRM on meaningful use. We find it generally consistent with the overall framework proposed by the Meaningful Use Workgroup and approved by the HIT Policy Committee in July, 2009. The Committee respectfully submits the recommendations contained in this letter, which we believe would strengthen the criteria and respond to many of the issues and concerns which were made known to the Committee.

We remain available and willing to assist the Office and the Department in any way we can.

Sincerely,

/Paul Tang/ /George Hripcsak/
Paul Tang George Hripcsak

Chair, Meaningful Use Workgroup

Co-Chair, Meaningful Use Workgroup