February 25, 2011

Mr. Joshua Seidman
Office of the National Coordinator for Health Information Technology
Mary Switzer Building
330 C Street, SW, Suite 1200
Washington, DC 20201

RE: Comments on the Health Information Technology Policy Committee's (HITPC) proposal for Stage 2 of the Meaningful Use of Electronic Health Records (EHRs)

Dear Mr. Seidman:

The undersigned organizations appreciate the opportunity to provide feedback on the Health Information Technology Policy Committee's (HITPC) proposed set of requirements for Stages 2 and 3 of the Medicare/Medicaid Electronic Health Record (EHR) meaningful use incentive programs. We understand that although the Stage 3 objectives are included in the proposal, HITPC is primarily interested in comments on the proposed Stage 2 measures. In addition to this letter, attached is a matrix that summarizes the proposed measures, and our specific comments for each proposed Stage 2 and 3 measure. In addition, we have included feedback in response to the specific questions posed by the HITPC. **Physicians are diligently working towards incorporating well-developed EHRs into their practices to improve quality of care delivery, enhance patient safety, as well as support practice efficiencies. Inflexible, overly ambitious incentive program requirements will only hinder health IT transitions underway today. Promoting greater flexibility to meet meaningful use requirements will help us achieve the desired outcome for the Medicare/Medicaid EHR incentives—accelerating the widespread use of technology to improve our nation's health care delivery system.**

We recognize that the widespread proper use of health IT will help transform health care by facilitating health information exchange, reducing inefficiencies, and improving the quality of care. Financial incentives linked to reasonable, achievable measures will encourage the use of EHRs, but aggressive, burdensome requirements will not. Even the President's Council of Advisors on Science and Technology (PCAST) report, "Realizing the Full Potential of Health Information Technology to Improve Healthcare for Americans: The Path Forward," published on December 8, 2010, acknowledged this concern:

> **We emphasize that there is a potential concern with pushing too many requirements into meaningful use. The concern is that this will create too onerous a burden for many healthcare providers, especially smaller physician offices that already may lag behind in adoption.**

Another key barrier to health IT adoption is the fact that much of the infrastructure and the tools required to achieve the desired level of interoperability and information sharing remains to be built. The aforementioned PCAST report also states, "…current efforts at health data networking are at relatively small scale." Physicians look forward to the day when they can securely exchange information with other providers to enhance the quality and efficiency of the care that they provide to their patients. However, asking physicians to do more within an environment that is still not largely interconnected, and in which commercially available products cannot perform the required functions reliably, will simply result in additional financial and administrative burdens, including the use of time-consuming dual processes—paper and electronic. Another

important factor to consider is the financial support for creating and maintaining information exchanges and ensuring that physicians are not burdened with funding these exchanges.

While we support a staged approach to the EHR meaningful use incentive program, we believe that this approach must take into account the current technological realities and the additional financial and administrative costs that will be incurred by physicians to meet all of the measures required by the program. Therefore, in order to maximize physician participation in the Medicare and Medicaid EHR meaningful use incentive programs, we firmly believe the following actions must occur:

(1) The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator (ONC) should survey physicians who elected to participate and those who elected not to participate during Stage 1 of the incentive program and identify barriers to and solutions for physician participation prior to moving to Stage 2;
(2) Measures for meeting meaningful use should factor in appropriate use. Reasonable exclusions for many requirements should be included so that a physician can opt out of the measure if the measure has little relevance to the physician's routine practice;
(3) Prior to moving a measure from the Stage 1 menu set to the core set for Stage 2, or prior to adding new measures, the expected impact, the expected value, risks (both clinical and administrative), evidence of efficacy, administrative burden, costs to physicians, and technological standards of the move should be thoroughly assessed and publicly vetted. Any proposed new measure should initially be in the menu set of options;
(4) High thresholds should be avoided for objectives that cannot be met due to the lack of available, well-tested tools or bidirectional health information exchanges; and
(5) Measures that require adherence from a party other than the physician should be removed (e.g., patient's accessing patient portal, labs reporting test results).

Evaluation of Stage 1 participation rates

We believe it will be critical for CMS and ONC to create a mechanism to evaluate the progression of meaningful use objectives and measures, as well as the costs of adoption and upgrades of technology. Evaluating both the ability of physicians, EHR vendors, and the industry as a whole to meet measures and objectives, as well as associated costs, should be part of any decision-making process to move from one stage to the next.

The evaluation should include a process that enables physicians to provide feedback on the value of the Stage 1 measures to their practice. There should also be a mechanism that allows physicians to disclose to all relevant parties, including EHR vendors, when: structured data fields are not available or are needed in order to meet measures; patient safety concerns/issues with EHR capability arise; functionality or specifications are lacking; administrative complications occur in implementation, formatting, and other usability issues are uncovered; and actual computer errors stemming from the programs themselves, as well as lack of interoperability between programs, are discovered.

Solutions for overcoming Stage 1 barriers should also be incorporated in Stage 2. For example, if survey results show that specialists decided not to take part in the Stage 1 meaningful use EHR incentive program because many of the Stage 1 measures did not apply to their routine practice, then Stage 2 should allow physicians to opt out of any measures that do not apply to their routine practice. **We recommend that CMS and ONC survey physicians who elected to participate**

and those who elected not to participate during Stage 1 of the incentive program and identify barriers to and solutions for participation prior to moving to Stage 2.

Most measures should include an exclusion category

A major criticism from physicians, especially specialists, regarding the Stage 1 meaningful use measures is the fact that many of the measures are primary care focused and lack an exclusion category for physicians who determine that the measure has little relevance to the physician's routine practice. Eight of the 15 Stage 1 core measures and 3 of the 10 Stage 1 menu options do not include an exclusion category. Many of the exclusions for measures under both the core and menu sets do not allow an exemption for physicians who do not routinely perform the activity described. From both a clinical and legal standpoint, physicians will be reluctant to take part in the Medicare or Medicaid EHR incentive program if they are being required to record data in their EHRs that they typically do not collect or that is not relevant to their scope of practice or the services that they provide to their patients. **We strongly recommend that many of the measures for Stage 2 include an exclusion option so that a physician can opt out of the measure if the measure has little relevance to the physician's routine practice**.

Inclusion of each measure should be carefully evaluated

HITPC is recommending that the following Stage 1 measures from the menu set be moved to the core set for Stage 2:

- Implement drug formulary checks
- Incorporate lab results as structured data
- Generate patient lists for specific conditions
- Send patient reminders
- Medication reconciliation
- Summary care record
- Submit syndromic surveillance
- Provide patient-specific educational resources

And, HITPC is also recommending inclusion of the following new measures for physicians:

- Record advance directive
- Enter electronic notes
- Use secure online messaging
- Record patient communication preference
- Offer electronic self-management tools
- Personal Health Record (PHR) data exchange
- Patient care experience reporting
- Patient capability to upload data into EHRs
- List care team members in EHR
- Record longitudinal care plan
- Submit notifiable conditions using a reportable public-health submission button
- Submit patient-generated data to public health agencies
- Submit reportable lab data

New measures should be initially placed in the menu set for Stage 2. Many of these proposed new measures (e.g., listing of care team members, recording of a longitudinal care plan) require further definition and development and need to be evaluated prior to being moved from the menu to the core set. To support the suggested pathway of accelerated use of specific features of certified EHRs as a major indication of meaningful use (e.g., incorporating lab results as structured data), the following assessment must occur and be publicly vetted before moving measures from the menu set to the core set or including new measures:

- Expected impact
- Expected value
- Risks (both clinical and administrative)
- Evidence of efficacy
- Administrative burden
- Requirements and/or candidates for standards, definitions, value sets are considered by the Health IT Standards Committee (HITSC)

Under the HITPC's proposal, there is no distinction between menu and core measures, and there are no exclusions. We strongly recommend: 1) retaining the menu option, 2) if the assessment reveals that evidence is lacking on a measure's efficacy, then Stage 1 menu measures should continue to be listed in the menu set, and 3) before any new measures are added to Stages 2 and 3, they should be fully evaluated based upon the above-mentioned assessment criteria.

<u>High thresholds should be avoided for objectives that cannot be met due to the lack of bidirectional health information exchanges</u>

There must be a reliable, accurate interchange mechanism for physicians, other health care professionals, hospitals, and other health care entities to share health information about patients, otherwise all of these health care partners will be overwhelmed with manual entries of the same data, which conflicts with a main goal for using EHRs—to reduce costs, create efficiencies, and improve care coordination by allowing information to be shared more easily among physicians' offices, hospitals, and across health systems. Furthermore, adopting additional requirements that hinge on data exchange when the infrastructure necessary to support these exchanges is still very limited will deter participation in these incentive programs.

Similar to the Stage 1 measures, Stage 2 also requires a significant amount of manual data entry by physicians and their office staff in order to meet meaningful use measures. For example, both Stage 1 and Stage 2 measures include computerized physician order entry (CPOE) and do not require that the orders be transmitted electronically because of the lack of bidirectional exchange capabilities between physicians and hospitals, physicians and pharmacies, physicians and laboratories, physicians and state public health agencies, etc. Health care partners must be capable of exchanging the requisite data and that data must be presented in a way that is understandable to the physician. Until the national, regional, and local infrastructures have been substantially developed and tested to allow for the secure electronic exchange of patient health information, the threshold requirements should remain low for meeting measures that still can only be met through manual data entry. As experienced with the Medicare Physician Quality Reporting System (PQRS) incentive program implementation, high threshold requirements are problematic. Due to program errors, CMS decided to reduce the PQRS reporting sample requirement from 80 percent to 50 percent for 2011 and is adding an appeals process for those physicians who fail to qualify for incentives that they believe they are entitled to.

We recommend that the proposed high threshold requirements for CPOE, incorporating lab results, and similar measures be reduced. For example, requiring physicians to enter into their EHR at least one medication and one lab or radiology order for 60 percent of their unique patients who have at least one such order, will require physicians to expend significant time and resources to manually gather information that spans both electronic and paper-based systems. In the case of referrals, it is typical for specialists and independent labs to require their own paper form to be completed by the referring/ordering physician. Therefore, entering the order electronically through CPOE would then need to be followed up with a manual process involving a paper form. Furthermore, decision support for ambulatory EHRs is still very basic. Until there is a bidirectional exchange of data and robust decision support, we do not believe the value of CPOE can be fully realized just through manual entry of most orders. **We recommend that the thresholds for CPOE and similar measures that cannot be met due to the lack of bidirectional health information exchanges be significantly lowered.**

Measures requiring adherence from a party other than a physician should be removed

Any measure that holds physicians to an objective that is beyond their control should be removed. For example, physicians cannot force a patient to use a PHR or a patient portal. Without an incentive, many patients are unlikely to participate in this objective regardless of their ability to access the Internet. While patients should be informed of the benefits and uses of a PHR, physicians should not bear the risk of being penalized for something that is an independent decision made by the patient. **We recommend that measures that require adherence from a party other than the physician should be removed (e.g., patient's accessing patient portal, labs reporting test results).**

Responses to specific questions posed by HITPC

1. The definition for an electronic progress note should be broad and flexible enough to accommodate all specialties and all types of clinical encounters. Progress notes are written in a variety of formats and detail, depending on the clinical situation at hand and the information the physician believes is relevant to record.
2. We strongly support patients' access to their clinical information including patients with disabilities. Unfortunately, the direction HITPC has taken requires a one-size-fits-all approach to qualify for incentives. We strongly urge the HITPC to allow physicians who treat patients with disabilities as well as physicians who treat hard to reach populations (e.g., rural, homebound) to use technologies that best allow them to meet their patient's needs and allow their patients to best communicate with their physician.
3. Physicians should have the latitude to deploy methods/technologies that enable them to best meet the needs of their patients. Furthermore, they should not be required to purchase systems that contain components that they will rarely or never use. For example, physicians should be allowed to use certified EHR modules to qualify for meaningful use incentives given that such bundles of modules may be cheaper and easier to implement.
4. Physician views on PHRs are often positive, but nuanced, demonstrating awareness that PHRs pose unique risks and benefits. In a set of surveys of patients and doctors that the American Medical Association (AMA) and the Markle Foundation conducted in 2008, a large majority of those patients who had used a PHR felt they were valuable, but very few had used them and just under half said they would be interested in trying to do so. Among physicians, half thought PHRs could empower patients to participate in their care and just under half said they would be willing to use PHRs in their clinical work. Fewer than one quarter, however, agreed that using PHRs would improve their relations with

patients (one-third disagreed) and only about one third agreed with the general statement that PHRs would, "improve the quality of care." Meanwhile, large majorities worried that PHRs might contain incorrect information, that privacy protections were not adequate, and that patients might omit important information from their PHR. More recently, data from these surveys were published in *Health Affairs* (February 2011) showing that while 64 percent of physicians had never used a PHR, 42 percent indicated they would be willing to try, though there were differences according to physician location, gender and practice type. Furthermore, while many physicians are willing to try using a PHR, it is critical to note that according to HHS' own data, only 4 percent of physicians have a "fully functional" EHR and only 13 percent have a "basic system." We continue to believe that the focus of the EHR incentives should remain on adoption of well-tested, basic EHR systems.

5. While we support the idea that high performance on quality measures is consistent with meaningful use, performance thresholds have not been determined for many quality measures including all Physician Consortium for Performance Improvement (PCPI) measures. Given the current state on reporting on quality measures, we would not recommend this approach at this time.
6. Given that a group practice reporting option is available under both the Medicare e-prescribing and the Physician Quality Reporting System (PQRS) incentive programs, we support a group practice reporting option for meaningful use. This would be an opportunity for CMS to better align multiple incentive programs underway today.
7. We do not support making the advance directive measure a required measure under the core set. An exemption should be offered with the advance directive measure so that if recording an advance directive is not within the scope of a physician's practice, the physician could indicate that an exemption applies for meeting this particular measure. Please see our comments in the attached matrix on this topic.
8. We believe that attention needs to be spent on reaching consensus on the appropriate elements that should make up a care plan, clinical summary, and discharge summary. Here are potential elements for assessment purposes: (a) elements that could comprise a care plan include: care team member, diagnoses, medications, allergies, goals of care, data captured by remote monitoring devices (in and/or out of range), and interactions and interventions by care team members; (b) elements that could comprise a clinical summary include: encounter date and location, reasons for the encounter, providers, problem list, medication list, allergies, procedures, immunizations, vital signs, diagnostic test results, clinical instructions, orders (future appointment requests, referrals, scheduled tests), gender, race, ethnicity, date of birth, preferred language, advance directives, and smoking status; and (c) electronic discharge instructions could include: a statement of the patient's condition, discharge medications, activities and diet, follow-up appointments, pending tests that require follow-up, referrals, and scheduled tests.
9. Certified EHRs today must be able to accommodate any new measures for Stages 2 and 3 without requiring costly, time consuming upgrades. We recommend that new measures be initially placed in the menu set for Stage 2. Please also review our recommendations above under "Any proposed new measure should be initially placed in the menu set of options." We furthermore believe that more flexibility is needed for meeting measures to ensure that a specialist (e.g., radiologist, anesthesiologist, pathologist, home care physician, etc.) whose services do not fit neatly into the current set of proposed measures is able to participate or benefit from the incentive program. The proposed requirements will unduly exclude physicians who do not come into direct contact with patients like pathologists and radiologists. Nonetheless, these specialists' use of health IT is critical as is their ability to begin exchanging health information with other health care providers. Greater flexibility is also needed in the eligibility requirements to accommodate

hospital-based health care professionals who provide a substantial amount of services within their office-based practices so that they are also eligible for incentive payments based upon the adoption and use of qualifying EHRs in their offices. We also believe that incentives or relevant meaningful use requirements are warranted to encourage hospitals, Ambulatory Surgery Centers (ASCs), and office-based surgical practices to invest in systems such as those used by anesthesiologists (known as AIMS).

10. The following new objectives being considered for Stage 3 are ambitious:
    - Offer electronic self-management tools to patients with high priority health conditions
    - EHRs have capability to exchange data with PHRs using standards-based data exchange
    - Patients offered capability to report experience of care online
    - Offer capability to upload and incorporate patient-generated data into EHRs and clinician workflow
    - Public health button. E-reporting if possible, otherwise generate another form (e-fax) and send
    - Patient-generated data submitted to public health agencies
    - Submit reportable lab data

The assumptions for these aforementioned objectives are that: the majority of physicians, hospitals, and other health care professionals are using certified EHR technology, bidirectional data exchange capabilities amongst health care partners readily exist, and the majority of patients are using PHRs, accessing their health information online, communicating with their health care providers online, using electronic self-management tools, and understand measures relevant to their care. The above-mentioned activities must occur in order for the proposed new objectives for Stage 3 to be achievable.

Conclusion

We thank you for the opportunity to provide feedback on HITPC's proposed measures for Stages 2 and 3. Encouraging physician participation in the EHR meaningful use incentive program is critical to ensuring widespread EHR use; however, the requirements for participation must be realistic and attainable. We are committed to significantly increasing EHR adoption and ensuring that all eligible practices, especially smaller practices, are able to take advantage of the EHR incentives. Should you have questions about these comments, they can be directed to Mari Savickis at mari.savickis@ama-assn.org or 202-789-7414.

Sincerely,

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 Ophthalmology
American Association of Neurological Surgeons
American Academy of Neurology
American Academy of Ophthalmology
American Academy of Otolaryngology-Head and Neck Surgery
American Academy of Sleep Medicine

American Association of Clinical Endocrinologists
American College of Emergency Physicians
American College of Osteopathic Surgeons
American College of Physicians
American College of Rheumatology
American College of Surgeons
American Congress of Obstetricians and Gynecologists
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Osteopathic Association
American Osteopathic Academy of Orthopedics
American Psychiatric Association
American Society for Clinical Pathology
American Society for Gastrointestinal Endoscopy
American Society for Radiation Oncology
American Society of Anesthesiologists
American Society of Cataract and Refractive Surgery
American Society of Plastic Surgeons
Heart Rhythm Society
Congress of Neurological Surgeons
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Interventional Radiology
Society for Vascular Surgery
The Endocrine Society