March 15, 2010

Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: Medicare and Medicaid Programs; Electronic Health Record Incentive Program; RIN 0938–AP78; CMS–0033–P; 42 CFR Parts 412, 413, 422, and 495

Dear Acting Administrator Frizzera:

We, the undersigned organizations, are pleased to provide comments on the proposed rule for implementing the Medicare and Medicaid electronic health record (EHR) incentive programs. We appreciate the Centers for Medicare & Medicaid Service's (CMS) efforts to promptly issue a proposal for EHR "meaningful use" objectives and measures that must be met by eligible physicians to ensure receipt of the financial incentives specified in the "American Recovery and Reinvestment Act of 2009" (ARRA), which became law on February 17, 2009. **Physicians are deeply supportive of and committed to incorporating well-developed EHRs into their practices to improve quality of care delivery, enhance patient safety, as well as support practice efficiencies. To facilitate this transition, we want to ensure that there is widespread adoption and meaningful use of EHRs by physicians. We do, however, feel strongly that the Stage 1 criteria proposed by CMS for achieving meaningful use of EHRs is too aggressive and if adopted, will deter many physicians from participating in the Medicare and Medicaid incentive programs. This runs counter to the intent of ARRA, which clearly indicated that demonstrating meaningful use should progress over time.**

When implemented properly in a highly connected environment, widespread EHR 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. We must realize that the full potential of EHR use takes time, including the following key capabilities: (1) utility (e.g., order entry); (2) communication (e.g., physician to physician, physician to patient, physician to pharmacist, physician to other care settings and systems); (3) care coordination functions (e.g., medication management, including medication reconciliation, the timely transfer of patient information between sites of care, and providing notice of patient discharge plan and summary); (4) interface capabilities (e.g., enable interfaces within setting/site/system of care and with other settings/sites/ systems of care); and (5) abilities to facilitate the understanding of a patient population, patient demographics, patient conditions, diseases, and medical needs in order to enhance the quality and efficiencies of care. Successful integration of EHRs and health IT into patient care takes time and depends on whether or not the methodology employed to

achieve integration enhances physician performance and accurately reflects and supports the work of patient care.

Need for Reasonable Timelines and Criteria for Stage 1

The "bar" for demonstrating meaningful use during Stage 1 should not be set too high or too low. The goal of widespread EHR adoption and use will be undermined if the majority of physician practices, especially smaller ones, determine that they will be unable to meet and attest to the Stage 1 EHR incentive program measures and decide not to take part in the incentive program. The timelines and criteria for demonstrating meaningful use must factor in the expense and time to transition a physician practice to an EHR environment, the interruption of existing workflows, changes in patient-physician communication techniques, and the interaction between Practice Management Systems (PMS) and EHRs. CMS should also keep in mind that the majority of the proposed measures will require significant EHR use, manual calculations, software programming, training, and information exchange, in order to attest to the accuracy and completeness of metrics, including numerators, denominators, and exclusions. The expected manual review and counting of records to meet most of the proposed measures is highly burdensome and takes away from patient care. **Percentage threshold reporting should only be required when the EHR has the ability to automatically calculate all metrics that are required to be reported and that this can be easily done by the physician.**

The vast majority of physicians practices are comprised of five or fewer physicians. Encouraging physician adoption of health IT, especially small physician practices, is critical to ensuring widespread EHR use. Studies of EHR adoption clearly show that it takes more time for smaller practices to adopt and implement EHRs because they have fewer resources and support. Aggressive timelines and criteria during the initial stage of the incentive program will only serve to undermine this effort. Some government officials have relayed that complex measures and high reporting thresholds are needed to discourage EPs from switching back to the use of paper during this transition to EHRs. We are very troubled by this assertion. Physicians are deeply supportive of and committed to incorporating well-developed EHRs into their practices to improve quality of care delivery, enhance patient safety, as well as support practice efficiencies. It is also very unlikely that after physicians make a significant up front investment in health IT and changes to their workflow that they will revert back to manual processes. We believe that the larger concern should be deterring the purchasing of costly EHR products that fail to improve physician workflow, patient care, and practice needs. Industry experts have cited that such failures have adversely affected EHR adoption rates ranging from 50 to 80 percent.

It is also important to keep in mind that health care professionals who make house calls to the home-limited elderly, and those in many rural areas do not have access to the proposed technology at the point of care. Many health care professionals who serve vulnerable patient populations will not be able to take advantage of the EHR incentive

programs because of the lack of broadband internet access. Funding is needed to construct, operate, and maintain broadband infrastructure in these underserved areas.

Need for Small Physician Practice Representation on Health IT Policy Committee

We have been and continue to be actively engaged with CMS, the Office of the National Coordinator (ONC), and the Health IT Policy and Standards Committees, to provide recommendations and feedback on how we believe an achievable and predictable pathway toward meaningful use of EHRs can be developed that would enable eligible physicians in all sizes of practices and specialties to take advantage of the financial incentives authorized by ARRA. However, we are very concerned that there is currently no member of the Health IT Policy Advisory Committee—the advisory body established under ARRA to recommend a framework to the U.S. Department of Health and Human Services (HHS) for the development and adoption of a nationwide health information infrastructure—who represents small physician offices, despite the fact that small physician practices represent 80 percent of all outpatient office visits. We are also concerned that several workgroups that provide recommendations to the Policy Committee are led by the same Chairs and Co-Chairs, which may not allow for sufficient diversity of opinions. Immediate steps should be taken to include representatives from small physician practices in future meetings.

Need for Feedback Loop on Performance

We also believe it is critical that physicians receive feedback on their performance so that they know if they are meeting the criteria for the incentives. **We must avoid the pitfalls experienced with the Physician Quality Reporting Initiative (PQRI) program.** Experiences with the PQRI program have demonstrated the difficulty of successfully reporting on just three measures. Significant physician outreach and education will be critical to ensure that all eligible physicians have the information they need to begin the process of meaningfully using their certified EHRs. We welcome the opportunity to work with CMS on physician outreach and education initiatives and materials on these important incentive programs in order to accelerate the widespread adoption and implementation of EHR systems, modules, and tools. **We believe it is essential that CMS and the states establish a feedback mechanism so that EPs can be assured early on that the information they report on through attestation has been successfully submitted and received.**

Staged Approach to Achieving Meaningful Use

We strongly agree with CMS' proposal for establishing a staged approach to achieving "meaningful use" of EHRs. In this way, eligible professionals (EPs) are provided a predictable pathway, enabling them to plan, including consideration of practice workflow changes, and to engage in critical discussions with EHR vendors regarding functionalities. To support this, we strongly recommend that the focus of Stage 1 for the health IT functionality measures be on data entry (e.g., problem list, medication list) and structured data (e.g., enable EHR functionality for drug-drug, drug-allergy, drug

formulary checks). If achieved consistently and accurately, a more seamless use and reporting of quality measures will result. **Therefore, we believe Stage 1 should be redefined and the proposed criteria should be segmented into two years to provide more flexibility on functionality measures and selection/awareness of quality measures as follows:**

Stage 1-First Payment Year. 1) EPs should only be required to attest to meeting at least five of the health IT measures, including the proposed requirement to maintain an up-to-date problem list, at revised thresholds discussed below. A problem list presents the diagnosis codes and other information necessary to understand the denominator elements for quality measure reporting (e.g., diagnosis codes for a patient qualify the reporting of a particular measure). A problem list, when stored in a structured format, helps ensure diagnosis information is appropriately utilized in determining quality measure reporting within an EHR. 2) EPs should only have to attest that they have selected three clinically relevant quality measures, if appropriate, and have downloaded and reviewed the Level 1 (human readable) measure specifications for these measures. The attestation should only require EPs to attest that, to the best of their ability, they are: entering the required data elements for quality measure reporting where those fields exist in the EHR; providing feedback to the EHR vendor where structured data fields are not available; and reporting to CMS and the appropriate measure developer any concerns/issues with EHR specifications. For those EPs unable to identify three clinically relevant measures with Level 1 measure specifications *adopted* under the incentive programs, they would attest that less than three or none apply for 2011.

Stage 1-Second Payment Year. 1) EPs should only be required to attest to meeting at least five health IT measures. 2) EPs should only have to attest that their EHR system has produced an automated report providing aggregate performance information (e.g., numerators, denominators, exceptions) for all patients for which the clinical quality measures they selected in Stage 1 apply, and they report to CMS (as well as measure developers) any identified issues with accuracy and completeness.

Use of Numerators and Denominators

Seventeen of the twenty-five measures require the use of numerator and denominator data in order to establish that an objective has been met. We are very concerned that CMS' proposal to use numerators and denominators could significantly jeopardize physicians' ability to meet the incentive program requirements. **The proposed use of numerators and denominators will require significant manual calculations on the part of physicians since there are no automated reports that can capture all of the orders, lists, results, conditions, and other health related information that must be tabulated. Percentage threshold reporting should only be required when the EHR has the ability to automatically and easily calculate all metrics that are required to be reported.**

Health IT Functionality Measures

The majority of health IT measures would require use of a numerator and denominator to meet the objective. The problem with this approach is that there is no simple way to tabulate this data. For example, in order to meet CMS' proposed requirement that physicians send reminders on preventive/follow-up care to all patients over 50 years of age, they would need to keep track manually of every phone call, letter, and fax, in addition to reminders sent electronically. Even in cases where the measure is largely performed electronically, such as in the case of maintaining problem lists, a lengthy and potentially costly process involving the creation of customized automated reports may be needed in order for physicians to meet the measure.

The certification interim final rule (IFR) calls for certified EHRs to, "electronically generate, upon request, a patient reminder list for preventive or follow-up care according to patient preferences based on demographic data, specific conditions, and/or medication list." However, the IFR does not require EHRs to have the ability to tabulate the data required by EPs to demonstrate they have met the objective. Use of numerators and denominators was also not supported by the Policy Committee's Certification and Adoption Workgroup that met on February 17, 2010, and recommended that: 1) the certification IFR should include certification criteria for a section called "Reporting Metrics," which would ensure automatic calculation of all metrics that are required to be reported; and 2) the reporting process for Stage 2 of meaningful use should not require manual review of records or subjective judgments. Even the Workgroup agreed that retaining the proposed manual method for percentage threshold reporting could be a serious deterrent for physician participation in this program. **We therefore, urge CMS to remove any required use of numerators and denominators to meet the applicable Stage 1 objectives and measures.**

Quality Measures

The focus on data entry and health IT functionality measures lays the foundation for quality measures. For Stage 1, Year 1, it will be very difficult for physicians adopting and implementing an EHR system to attest to the accuracy and completeness of numerators, denominators, or exceptions for clinical quality measures. Our research shows that testing is needed to be certain that for each measure EHR programmed analytics identify all patients who meet denominator, numerator, and exceptions criteria. Analytics may exist, but not accurately capture all patients who should be included in each measure component. Feedback provided by the EPs to CMS and the measure developers during this phase will be invaluable for future success. Putting these reports—accurate, timely reports—into the hands of practicing EPs, is a critical step prior to exporting of data. EPs can act upon data and concentrate on quality improvement specific to patient care issues. Feedback regarding the capture and use of this data to CMS (and measure developers) will be invaluable for future success. We anticipate that under Stage 1, Year 2, physicians will be sufficiently familiar with Level 1 (human readable) eMeasure specifications, and therefore will have a better ability to report the data using numerators, denominators, and exceptions through attestation.

Evaluation Needed Prior to Moving from One Stage to the Next

We believe it will be critical for CMS or ONC to create a mechanism for evaluating the progression of meaningful use objectives and measures, as well as the costs of adoption, prior to moving from Stage 1 to Stage 2. Evaluating both the readiness of the industry in meeting measures and objectives, as well as costs, should be part of any decision-making process for moving from one stage to the next.
According to CMS, the average adopt/implement/upgrade cost is $54,000 per physician FTE, while annual maintenance costs average $10,000 per physician FTE. CMS has not fully factored in costs associated with adopting the requirements proposed in this rule. Physicians who have already adopted EHRs may need to purchase newer software, hardware, and/or interface capability, placing additional costs on the practice. We are very concerned that these requirements would require substantial investments in several interfaces and customizations, and that this could also be a significant factor in deterring adoption. Furthermore, physicians would need to make these investments upfront and even those eligible for the maximum incentives would experience costs that could exceed the maximum incentives available. Also, physicians, particularly those treating Medicare patients, who do not meet the criteria for the maximum incentives (based on allowed charges), will likely incur the same software/hardware costs as those who are eligible for the maximum payment amounts. We are equally concerned that in addition to the typical six month to a year timeframe associated with workflow interruptions, physicians could experience diminished productivity over time due to the volume of measures. We believe that it is critical that CMS/ONC monitor and evaluate the costs of adopting the objectives and measures and factor this into any decisions for requirements for future stages. Adopting all of the twenty-five objectives and measures could be extremely cost prohibitive.

An evaluation will allow for a more predictable pathway to widespread use of EHRs and a nationwide health information network. **Therefore, prior to moving to Stage 2, we strongly recommend that CMS/ONC fully evaluate the following critical interrelated pieces:**

- The progress being made by EPs and hospitals in meeting the incentive program requirements;
- 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 (e.g., 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;
- Health care providers have fully integrated EHR use into their clinical workflow;
- Any barriers that exist to implementing certain requirements including costs; and
- CMS is able to address lessons learned from Stage 1 experiences.

Education and Outreach Plan is Critical to Ensure Success of the Incentive Programs

HHS should develop a multi-pronged communication process that includes, but is not limited to:

a. An easy-to-navigate website with a comprehensive FAQ section;
b. Toll-free telephone numbers to provide accurate information;
c. Regularly-scheduled "open door" seminars to provide updates and address participant questions;
d. Participation by HHS officials at industry conferences and forums;
e. Direct outreach to provider trade associations;
f. Specific guidance so that physicians know that the products (EHR systems and modules) they are purchasing will meet the incentive program requirements; and
g. Point people in each region.

We welcome the opportunity to work with CMS on physician outreach and education initiatives and materials on these vital incentive programs in order to accelerate the widespread adoption and implementation of EHR systems and tools.

Participation Requirements for EPs and Clarifications on Attestation

We agree with CMS' proposal to allow EPs, who qualify to participate under both the Medicare and Medicaid incentive programs, to switch between programs after their initial payment year. We also support CMS' proposal to permit EPs to reassign their incentive payments to their employer or to an entity with which they have a contractual arrangement. CMS should provide clear instructions on how the reassignment process works. We are concerned however, that the proposed rule calls for the qualifying EP to produce a Tax Identification Number (TIN) to which the EP's incentive payment should be made. While this will work for physicians who have a TIN, this will not work for many physicians who do not have a TIN, and are enrolled with Medicare or Medicaid through their social security number (SSN). **We urge CMS to accept the SSN in lieu of the TIN for those physicians who lack TINs to ensure that all eligible physicians are able to participate in the Medicare and Medicaid incentive programs. We agree with CMS' proposal that the attestation, which will include sensitive, identifying EP information, must occur through a secure mechanism to ensure that this information is not publicly disclosed or inappropriately used.**

For the first year, CMS will require attestation for meaningful use and the submission of clinical quality results. Should an audit reveal that the Medicare EP should not have qualified for the incentive, we request that CMS state in the final rule that as long as these attestations are done in good faith, the remedy will be the recoupment of an overpayment, and will not involve referral to the Office of Inspector General for the possible violation of the False Claims Act.

Initial EHR Reporting Period—90 Consecutive Days for the First Payment Year

We support CMS' recommendation to limit the reporting period for the first payment year. The proposed EHR reporting period—any 90-day continuous period within the first payment year—will provide the flexibility that practices need to transition their paper workflows to electronic ones. It is important to factor in that for an average practice to move from initial adoption of an EHR system to more robust use, it will take at least 12-18 months.

CMS states in the proposed rule, however, that they, "believe that there are considerations that distinguish the first payment year from the remaining payment years. The foremost being that once an EP or eligible hospital begins to meaningfully use certified EHR technology they are unlikely to stop." We strongly agree that once physicians make the financial and resource commitments associated with purchasing and using an EHR, as well as adjusting their workflow, they are unlikely to stop and return to manual processes. We believe that the initial years of meaningful use should be considered as the start up phase, and therefore, should take into account that physician practices vary in size, specialty, and location and will be in transition mode. Productivity and patient access to care could be significantly hampered during the initial adoption and use time period. The reporting period should not be lengthy and should be flexible enough to accommodate all eligible physicians during this critical transition period.

Definition for a Hospital-Based EP (§495.4)

We do not support CMS' proposed definition of a hospital-based EP because it will exclude many physicians who have purchased or plan to purchase their own EHRs. 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. Different EHR capabilities are needed for outpatient and inpatient care; therefore, some physicians who perform much of their care in an inpatient setting, still see patients in their office and have purchased their own EHR. They do not use the hospital EHR for clinic visits but instead use an ambulatory EHR. Often these ambulatory EHRs are "purchased" by the hospital entity and sometimes are even an integrated component of the inpatient EHR. However, in many cases they are completely separate EHR products and in all cases the implementation involves a focused, separate effort from the inpatient implementation. In too many health care

systems the inpatient EHRs are implemented and the ambulatory departments are void of an EHR due to the involved costs, resource needs, and complexity. Outpatient physician groups must invest significant effort for a successful implementation. These physicians must exert significant time and energy to plan and execute strategies that use the ambulatory EHR to improve quality of care.

We strongly recommend that CMS take into consideration whether a physician has contributed funding towards or will be contributing funding towards an EHR for their office practices. Although the hospital-based EP definition in ARRA mentions pathologists, anesthesiologists, and emergency physicians as examples of those who might furnish substantially all of their services in a hospital setting (whether inpatient or outpatient) using the qualified EHRs of a hospital, other specialists, not mentioned in ARRA, such as surgeons, radiation oncologists, etc., could be disqualified from the Medicare and Medicaid incentive programs due to the inflexible site of service parameters set in the regulations, despite the fact that they have contributed funding towards and use an EHR for patient care. Unless this definition is modified, practices who have already invested thousands or millions of dollars will not be eligible for these incentives.

We furthermore believe that Congress' intent to exclude certain hospital-based physicians was due to the assumption that the hospital would provide EHR technology to these physicians for meaningful use purposes. This is clearly evidenced in a letter sent by Senator Debbie Stabenow and sixteen other senators to HHS' Secretary Sebelius on February 9, 2010: "the purpose of Section 4101(a)(C)(ii) [of ARRA] was to prevent physicians from "double dipping" and receiving payments when their practice is primarily in a hospital setting…CMS did not follow our clear intent…this disregard for statutory language, conference report language, the congressional record, and letters of support is startling and will be devastating for our nation's providers." **We recommend that CMS revise the definition of hospital-based EP to indicate that hospital-based EPs who have contributed/are contributing funding towards a certified EHR and are able to attest to this, would also be eligible for incentives under the Medicare and Medicaid programs.**

We also believe it is critical that CMS create a mechanism by which physicians can be made aware of whether or not they are excluded from the incentive program. Most importantly, this information needs to be available to physicians prior to the start of the incentive programs. Furthermore, there needs to be a mechanism by which physicians can review these decisions, appeal them, and a process whereby physicians can alert CMS when their status has changed. For example, a hospital-based physician (e.g., hospitalist) who leaves his/her hospital-based practice for a non-hospital based practice should be able to notify CMS of his/her eligibility and take part in the incentive program. **We strongly urge CMS to: 1) develop a simple, web-based tool that allows physicians to determine their eligibility prior to the start of Stage 1; 2) establish an appeals process so that physicians can dispute any erroneous determination regarding their eligibility; and 3) permit physicians to revise their status, and thus eligibility, if it changes mid-year so that they can take part in the incentive program.**

We also urge CMS to ensure that the meaningful use objectives and measures for eligible hospitals include requirements for hospitals to enable hospital-based physicians, such as pathologists, anesthesiologists, or emergency room physicians, to be able to use hospital EHRs in a meaningful way as it pertains to their specialized practice. **Hospitals systems should be required to provide EHR technology that meets the needs of hospital-based physicians to enhance the quality, safety, efficiency of the care that these physicians provide to patients.**

Measures and Objectives (as described in Table 2: Stage 1 Criteria for Meaningful Use)

EP Objective 1: *Use Computerized Provider Order Entry (CPOE).*
EP Measure 1: *CPOE is used for at least 80 percent of all orders (e.g., medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services).*
Recommendation 1: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to perform at least one test of certified EHR technology's capacity to conduct CPOE.*

Although we support the use of CPOE, we do not support the 80 percent threshold requirement for Stage 1. CMS has proposed to define CPOE as "entailing the provider's use of computer assistance to directly enter medical orders (for example, medications, consultations with other providers, laboratory services, imaging studies, and other auxiliary services) from a computer or mobile device." We believe more clarification on the measure is needed. As for medications, while CMS states under this measure that such orders are not required to be exchanged electronically, the agency states under a separate measure (see measure 4 below) that EPs are required to electronically transmit at least 75 percent of their permissible prescriptions (non-controlled substances). Since prescriptions are a type of order, these two measure requirements are in direct conflict, therefore, clarification on this point is needed. It is also important for CMS to clarify that the term "medications" under the CPOE context means physician-administered drugs. Other operational definitions are required for terms used in this measure. Without clear and unambiguous definitions for clinical terms such as, "order," "test," and "result," it will be impossible for practices taking part in these incentive programs to report consistent information. Moreover, it is important to keep in mind that today there is no standardization of laboratory data and no standard way that a laboratory transmits results based on an order to EHRs. Very few physicians today are using CPOE in their offices largely because there is no one with whom they can exchange data (with the exception of prescriptions). According to a July 2008 *New England Journal of Medicine* study, "Electronic Health Records in Ambulatory Care – A National Survey of Physicians," only 4 percent of practices reported use of CPOE. We are very concerned that introducing CPOE into the outpatient setting too quickly will create duplicative work for physicians, risks diminished physician-patient communication, and may pose patient safety concerns.

Requiring physicians to enter 80 percent of all orders into EHRs will require EPs to expend significant time and resources to manually gather information that spans both electronic and paper-based systems. For example, 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 bi-directional 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.

A growing body of evidence has shown there are benefits to using CPOE. Most studies have focused on CPOE use in the hospital setting and many have focused on the benefits of preventing adverse drug events. CPOE is a disruptive technology that fundamentally changes the processes used to place, review, authorize, and carry out orders. Therefore, understanding workflows and redesigning inefficient processes are critical steps to ensuring successful adoption of CPOE. A sufficient amount of time is needed to ensure this is done both safely and efficiently. Research from the Agency for Healthcare Research and Quality (AHRQ) found that continuous, frequent training and retraining are critical to the success of inpatient CPOE initiatives, and this can be difficult for small and rural facilities (Inpatient Computerized Provider Order Entry (CPOE), AHRQ Publication No. 09-0031-EF, January 2009). While this study focused on hospitals, we believe the findings are also applicable to physician's offices.

As is the case with the introduction of any new technology, there is also the possibility for errors. Research has also found that while there are significant benefits to using CPOE in hospitals, its use can also introduce new errors. According to a *Health Affairs* article, in other countries where CPOE has been implemented in hospitals, "Implementation of CPOE is slower and more problematic than anticipated (adoption rates are 20 percent or less) and often poorly integrated, inducing new errors and generating frustration with user interfaces and repetitive tasks." Much less is known, however, about the impact of CPOE in the outpatient setting. While there are few studies on use of CPOE in the outpatient setting, several studies have researched the affect of physician computer use on the doctor-patient communication. One study in *the Journal of General Internal Medicine* found a negative impact on the visual, verbal, and postural connection between physicians and their patients when computers were introduced into the exam room ("Effects of Exam-room Computing on Clinician-patient Communication: A Longitudinal Qualitative Study," Frankel etc., August, 20, 2005). According to another study published in *Patient Education and Counseling*, "screen gaze" appeared to be particularly disruptive to psychosocial inquiry and emotional responsiveness, suggesting that visual attentiveness to the computer monitor rather than eye contact with the patient may inhibit patients from revealing sensitive or complete information relevant to their care. We believe that adequate training will be needed to help ensure physicians can incorporate use of computers in such a manner that facilitates physician-patient eye contact and does not disrupt good verbal communication.

We are also concerned about patient safety issues that could result from the diminished role of the physician-patient communication if CPOE is integrated into physician practices too quickly without adequate training. Communication failures resulting in medical errors do not occur exclusively between providers, but, can also occur between physicians and patients. Physician-patient communication failures are attributed to poor communication skills which generally include lack of patient understanding, barriers attributable to health literacy, and language and social barriers, things which could be exacerbated if CPOE is introduced too quickly into physicians' offices. According to a January 2008 Commonwealth Fund report, *Health Literacy Practices in Primary Care Settings: Examples from the Field*, generally speaking, patients with low health literacy are at greater risk of misunderstanding treatment recommendations, having problems in accurately taking prescription medications, and self-reporting lower health status and poorer health outcomes. Consequently, they have a 52 percent greater risk of being hospitalized. It is estimated that nonadherence, or failure to take medications, results in 125,000 deaths annually and costs an estimated $100 billion in treatments and lost productivity. The costs of limited health literacy could be immense. In the U.S. alone, the National Academy on an Ageing Society estimates that low health literacy results in annual costs of over $70 million, largely in increased and longer hospital visits.

An additional concern we have with the high threshold requirement for meeting CPOE measures in Stage 1 is the fact that CPOE systems can be costly. While Stage 1 does not call for CPOE use to involve any exchange of information (with the exception of prescriptions), we understand the expectation is that most orders will be exchanged electronically in future stages of the incentive program. In order to achieve this, an "advanced" system will be needed. According to the Center for Information Technology Leadership (CITL) study, "Value of Computerized Physician Order Entry in Ambulatory Settings," the functionality of a "basic" system is significantly different from more advanced systems. As the CITL report notes:

> Basic, Intermediate, and Advanced system classes differentiate along two main axes: ordering capability and decision support capability. All systems capture the same types of medication and diagnostic orders; systems are separated largely by their ability to transmit orders electronically. Basic Rx-Dx, for instance, is able only to record and print medication orders – essentially a computerized version of a traditional hand-written prescription. Advanced Rx-Dx, on the other hand, automates the entire order capture and transmission process through EDI, connecting ACPOE with pharmacy and pharmacy benefit manager systems.

In order to achieve this, an "advanced" system will be needed. CITL's study reported that the total costs of an advanced system for a single physician would be $505,400 over five years with a net cost of $365,715. CITL found intermediate systems resulted in cost savings to single practitioners and other larger groups over five years, however, these systems are not capable of result reporting (e.g., lab and radiology). While we believe that with time CPOE systems will come down in price, there will be significant financial and workflow challenges that will persist during Stage 1 and that adopting CPOE for Stage 1 will be a significant barrier for many physicians particularly the smallest ones.

We recommend that CMS revise the measure for CPOE for Stage 1 to indicate that EPs only have to attest having performed at least one test of certified EHR technology's capacity to conduct CPOE.

EP Objective 2: *Implement drug-drug, drug-allergy, drug formulary checks.*
EP Measure 2: *EP has enabled this functionality.*
Recommendation 2: *We support this measure.*

We support CMS' proposed objective and measure to require EPs to attest to enabling the functionality of their certified EHRs to allow for drug-drug, drug-allergy, drug formulary checks. We recommend that CMS press health plans and pharmacy benefit managers (PBMs) to ensure that drug-formulary information is accurate in real-time. Drug-formulary information is helpful, if it is accurate. We strongly believe that the availability of accurate, timely formulary and benefit information is critical to the value proposition of e-prescribing for physician practices. Current drug coverage, eligibility, and formulary information should be available on a real-time basis for a prescriber's review. As a result of the complexities of individual plan formularies and eligibility of benefits, the information provided to physicians is often outdated and lacks necessary detail, which can lead to higher co-pays and confusion for patients. Numerous physician practices that transmit prescriptions electronically indicate that they receive limited formulary and benefit information. Health plans, carriers, and pharmacy benefit managers should be required to provide accurate, timely, and complete formulary and benefit information so that the intended benefit of this objective can be fully realized.

EP Objective 3: *Maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®.*
EP Measure 3: *At least 80 percent of all unique patients seen by the EP have at least one entry or an indication of none recorded as structured data.*
Recommendation 3: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to attest that problem lists are up-to-date.*

Although we support the maintaining of an up-to-date problem list of current and active diagnoses, we do not support the 80 percent threshold requirement for Stage 1. We appreciate that a problem list is defined as "a list of current and active diagnoses as well as past diagnoses relevant to the current care of the patient." The inclusion of the term "relevant" allows physicians to collect pertinent information specific to a patient's particular course of treatment. We believe the key to advancing patient care is encouraging physicians to provide comprehensive care relevant to their patient's treatment(s). EHRs should have a "historical data file" that enables physicians to see the "life span" of the patient or an episode of care or chronic condition. Historical data is relevant to timely, efficient care. For example, a patient recently referred to another physician needs the patient's changes or adjustments to a specific medication over a year or more time and corresponding laboratory studies to better evaluate the patient's present status or a medical imaging history. If such data is available, the necessity to repeat tests can be determined quickly. However, with respect to data entry for meeting the specific measure, the measure as written is - on its face - an unrealistic

expectation, especially if every physician in the stream of care needs to gather the same information. **In addition, given the difficulties of manually calculating numerators and denominators and the lack of automated reporting, we recommend that in lieu of the 80 percent threshold requirement, the measure should only require EPs to attest that the problem lists for patients seen during the reporting period are up-to-date.**

EP Objective 4: *Generate and transmit permissible prescriptions electronically (eRx).*
EP Measure 4: *At least 75 percent of all permissible prescriptions written by the EP are transmitted electronically using certified EHR technology.*
Recommendation for Measure 4: *EPs should only have to attest to electronic prescribing at least 25 times during the reporting period using certified EHR technology.*

We strongly support the objective for generating and transmitting permissible prescriptions electronically, but we do not support the 75 percent threshold requirement for Stage 1. The threshold requirement of 75 percent is too aggressive for Stage 1 meaningful use criteria because it does not allow room for technical hindrances and other barriers to reaching full compliance. There are still many prescriptions that can not be electronically transmitted accurately due to technical barriers. For example, there is an exceptionally high rate of follow-up phone calls and faxes after certain electronic prescriptions (e.g., after insulin orders are sent electronically, lack of distinction between new orders and refills). In addition, many patients demand paper prescriptions for financial reasons (e.g., they are undecided as to whether to fill the prescription locally or through mail-order, they want to shop around for the best price, or they want time to purchase their medications to minimize or avoid the Medicare prescription "donut hole"). Moreover, in many areas of the country there still exist "independent, single store" pharmacies not affiliated with large chains. These local pharmacies may not have the resources necessary to invest in electronic prescribing or the capacity to receive electronic prescriptions. In addition, the expense of setting up electronic communication between an office-based EHR and multiple local pharmacies or national chains may be costly for some practices.

Another barrier is that several critical electronic prescribing standards have not been finalized (e.g., prior authorization, structured and codified SIG, clinical terminology). The Medicare Modernization Act (MMA) specifically mandates the development and promulgation of uniform standards, including prior authorization. Yet, not all of the standards, like prior authorization, have been deemed technically ready. The need for real-time prior authorization for physicians is particularly salient for physicians caring for Medicare patients given that most Part D plans require prior authorization for selected drugs. Physicians must be able to obtain real-time information about their patients' benefits and medications authorization status. Moreover, there are significant time and cost savings that could be realized by implementing a prior authorization standard. According to an analysis by Lawrence Casalino, MD, PhD of the Weill Cornell Medical College, the overall results of which were published in *Health Affairs*, $6.7 billion could be saved each year if there was a single prior authorization set of requirements. By

making these complex variables available on a real-time basis, this standard will further enable electronic prescribing.

We also believe that the proposed denominator for electronic prescribing, to count every "permissible" prescription ordered during the reporting period, will be too onerous to calculate given that prescriptions will continue to be prepared in a variety of ways—electronically transmitted, phoned-in, faxed, and written due to patient preferences and existing laws. In several states, laws and regulations permit e-prescribing of non-controlled substances but they are contradicted by state Medicaid requirements that require paper prescriptions. For example, in Rhode Island pharmacy regulations allow electronic prescribing, but state Medicaid regulations require that physicians prescribe drugs for these patients using a special three-part Medicaid prescription form. It will be very difficult and time consuming for EPs to perform a manual count on the voluminous number of prescriptions they issue on a daily basis.

For the 2010 Medicare e-prescribing incentive program, CMS only requires a physician to report the relevant electronic prescribing G code on 25 claims during a calendar year. CMS' rationale for significantly reducing the e-prescribing reporting requirements for 2010 was, "lowering this requirement simplifies the reporting burden, which would encourage eligible professionals to participate in this incentive program, and more importantly, to adopt an electronic prescribing system." We strongly agree that once physicians begin to e-prescribe, they will continue to e-prescribe when possible so there is no need to require burdensome reporting. **We strongly recommend that the proposed measure for e-prescribing for Stage 1 be to require EPs to attest to e-prescribing permissible prescriptions at least 25 times during the reporting period.**

While we understand that the DEA continues to work on finalizing standards for electronic prescribing of controlled substances, it is critical that workable standards are adopted and finalized as soon as possible. The fact that controlled substances are not yet eligible for electronic prescribing is a major impediment to adopting electronic prescribing. Physicians strongly prefer having one workflow method for the prescription process to the extent possible. As we move into an era when more and more physicians are using health IT, it is unacceptable that physicians must continue to rely on bifurcated process involving paper prescriptions for controlled substances and electronic ones for other prescriptions. When the DEA adopts the final standards, physicians and vendors will need adequate time to implement these changes. **We also urge CMS to continue to work with the Drug Enforcement Agency (DEA) to come up with a solution for enabling the electronic prescribing of controlled substances that is practical, functional, secure, as well as affordable for physicians.**

EP Objective 5: *Maintain active medication list.*
EP Measure 5: *At least 80 percent of all unique patients seen by the EP have at least one entry (or an indication of "none" if the patient is not currently prescribed any medication) recorded as structured data.*
Recommendation on Measure 5: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to attest that medication lists are up-to-date.*

EP Objective 6: *Maintain active medication allergy list.*
EP Measure 6: *At least 80 percent of all unique patients seen by the EP have at least one entry (or an indication of "none" if the patient has no medication allergies) recorded as structured data.*
Recommendation on Measure 6: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to attest that medication allergy lists are up-to-date.*

Although we support the maintaining of active medication and medication allergy lists for Stage 1, we do not support the 80 percent threshold requirement for Stage 1. The expected manual review and counting of records to calculate the numerators and denominators is too burdensome for Stage 1. Given the difficulties of manually calculating numerators and denominators and the lack of automated reporting, we recommend revising these measures for Stage 1 to indicate that EPs only have to attest that the medication and medication allergy lists are up to date.

EP Objective 7: *Record demographics.*
EP Measure 7: *At least 80 percent of all unique patients seen by the EP have demographics recorded as structured data.*
Recommendation on Objective 7: Modify to state, *Record demographics in either the practice management system (PMS) or EHR.*
Recommendation on Measure 7: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to routinely record demographics (defined as for at least twenty five relevant patients treated during the reporting period).*

While we support the objective for recording demographics, today, most physicians record this information in their practice management system (PMS). We understand that there will be PMS modules that physicians can purchase for their EHRs, and that interfaces will be readily available in the future to allow for connectivity between PMS and EHR systems. Until such time, physicians should not be burdened during Stage 1 with entering demographic data in both their PMS and EHR systems. This objective should be clarified to permit physicians to continue collecting demographic information in their PMS system. It is also important to note that physicians should have discretion in determining the types of demographic information to be collected. There may be state law or other restrictions about collecting information such as race and ethnicity. Physicians should also have the flexibility to collect other types of demographic information depending on the unique characteristics of their patient population (e.g., to assess health care disparities). **We, therefore, recommend that CMS modify this objective to state, "Record demographics in either the practice management system (PMS) or EHR." We also recommend revising this measure for Stage 1 to indicate that EPs only have to attest to routinely recording demographics (*defined as for at least twenty five relevant patients treated during the reporting period*) in lieu of the 80 percent threshold requirement.**

EP Objective 8: *Record and chart changes in vital signs. Record and chart changes in vital signs: height; weight; blood pressure; calculate and display the body mass index*

(BMI) for patients 2 years and older; and plot and display growth charts for children 2-20 years, including BMI.
EP Measure 8: *For at least 80 percent of all unique patients age 2 and over seen by the EP, record blood pressure and BMI; additionally, plot growth chart for children age 2 to 20.*
Recommendation on Objective and Measure 8: *Remove this objective and measure on vital signs from health IT functionality and include it in the clinical quality measures section.*

AND

EP Objective 9: *Record smoking status for patients 13 years old or older.*
EP Measure 9: *At least 80 percent of all unique patients 13 years old or older seen by the EP have "smoking status" recorded.*
Recommendation on Objective and Measure 9: *Remove this objective and measure on smoking status from health IT functionality and include it in the clinical quality measures section.*

Recording vital signs and smoking status belong in the clinical quality measure section; not the health IT functionality objectives and measures. These proposed objectives and measures on vital signs and smoking status should be added to the clinical quality measure primary care specialty group for EPs to select from. We strongly support the use of health IT to improve public health goals, however, for reasons outlined in more detail under the clinical quality measures section, a one size fits all approach, which requires the attesting to and/or reporting on metrics that are not clinically relevant to all EPs and their patients, does not help improve quality or practice workflow.

EP Objective 10: *Incorporate clinical lab-test results into EHR as structured data.*
EP Measure 10: *At least 50 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are in either in a positive/negative or numerical format are incorporated in certified EHR technology as structured data.*
Recommendation 10: *Remove 50 percent threshold requirement from Stage 1. EPs should only have to attest to the ability to enter lab results as structured data.*

While we support the incorporation of clinical lab-test results in EHRs, we do not support the 50 percent threshold requirement for Stage 1. We believe that this measure is too aggressive and burdensome to be placed in Stage 1 due to the costs of the electronic interfaces and manual processes that are needed. Incorporating lab test results manually into the EHRs as structured data will be burdensome and costly for practices, especially smaller practices that lack the resources for these manual interventions during the initial transition phase from paper records to electronic ones. Testimony was provided during the October 2009 Health IT Standards Committee hearing confirming the current lack of technology to accommodate this measure.

A number of operational impediments for integrating lab results into an EHR were also emphasized during the public hearing of the Health IT Policy Committee Information

Exchange Workgroup. Laboratory test results are rarely in a form that allows direct integration into an EHR. Customized interfaces between an EHR and lab systems (which are predominantly hospital-based), and with multiple lab vendors will be necessary, but do not exist on a widespread basis today and are costly to implement, test, and maintain for physician practices. The documentation of clinical lab results into EHR as structured data is dependent on the EHR vendor and the laboratory, not just the physician's use of the EHR. Moreover, smaller or rural practices may never achieve a sufficiently high priority (from the lab's perspective) to get an electronic interface. There have also been reports on the difficulties in matching patients within the lab compendium resulting in problems with erroneous transactions and results reporting to the correct patient.

According to testimony provided by eClinical Works in October 2009 to the Health IT Policy Committee, on top of a several week lab interface approval process physicians must undergo, "implementing, testing, and validating a lab interface for a practice with National Reference Lab companies take about anywhere from 4-14 weeks….As more physician practices start adopting EHRs, the backlog for Lab interfaces will grow significantly higher." In addition, Jonah Frohlich, Deputy Secretary of the California Health and Human Services Agency (also a member of the Health IT Policy Committee Information Exchange Workgroup) noted the "labor intensive and expensive" processes for developing a lab interface with an EHR. He explained that these processes typically are costs passed onto the EHR vendor and then to the physician purchasing the product and "typically with a $5,000 charge per lab interface." Unless a physician is a high volume customer, the lab "may not decide to support and interface at all."

Furthermore, we are concerned that if this requirement is finalized, in the absence of an interface, in order for physicians to meet this objective/measure, many physicians would have to manually key in the lab results into their EHRs. Manual data entry runs counter to larger goals of EHR adoption to improve efficiency and care processes and could increase the risk of data entry errors. Many physicians who use EHRs already today, especially smaller practices and rural ones, still can not get all of their lab tests into the EHR as structured data due to the costs of the interfaces that they cannot afford and that the labs/hospitals will not fund. Physicians should not be expected to key in lab results simply because there is no ability for the lab to send this data directly to the EHR. **Thus, manually calculating numerators and denominators to meet the 50 percent threshold requirement will make this measure highly burdensome to meet for Stage 1. We recommend that EPs should only have to attest to *the ability* to enter lab results as structured data in lieu of the 80 percent threshold requirement. CMS and ONC should also continue to press the industry to come up with the necessary technology to accommodate this measure.**

EP Objective 11: *Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, and outreach.*
EP Measure 11: *Generate at least one report listing patients of the EP with a specific condition.*
Recommendation for Objective 11: Modify to state, *Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.*

We support CMS' proposed measure for generating at least one report during Stage 1 listing patients with a specific condition, and recommend that the objective be edited to clarify that only one report needs to be generated during the reporting period to satisfy this measure. Physicians should have the discretion to generate lists dependent upon clinical relevance to their patient population, and EHR products should include the functionality that enables physicians to easily do this. The objective should be edited to state, "*Generate lists of patients by specific conditions to use for quality improvement, reduction of disparities, research, or outreach.*" This proposed objective and measure falls directly in line with the focus of the meaningful use of EHRs to be on data capture to assist the health care provider at the point of care during the initial stages of EHR adoption.

EP Objective 12: *Report ambulatory quality measures to CMS or the States.*
EP Measure 12: *For 2011, an EP would provide the aggregate numerator, denominator, and exclusions through attestation. For 2012, an EP would electronically submit the measures.*
Recommendation for Objective 12:

In implementing meaningful use of certified EHR technology to report on clinical quality measures and other measures specified by the Secretary, flexibility must be exercised in allowing physicians to determine which measures are clinically relevant, adequately specified, tested, and ready for use. It is from this perspective that we recommend the following revised stages for complying with clinical quality measure reporting.

Stage 1 / Year 1 (2011) -Attestation
- Select at least three clinical quality measures, if clinically appropriate, to report on for at least two years, or attest that no clinically relevant measures have been adopted under the meaningful use incentive program for 2011
- Download Level I (human readable) measure specifications
- Enter measure-specific data elements to the best of their ability
- Utilize EHR functionality to support entry of measure-specific data elements (e.g., problem list maintained, lab results entered)
- Feedback to CMS, EHR vendors, and measure developers regarding specifications, data entry, and missing fields for data entry if applicable

Stage 1 / Year 2 (2012)-Attestation
- EPs review measure reports from EHR systems
- Send summary report to CMS on accuracy and completeness of numerators, denominators, and exceptions for the measures that were selected in Stage 1, Year 1
- Provide feedback to CMS and measure developers regarding accuracy, completeness of eMeasure specifications (e.g., structured data fields are not available)

Stage II (beginning in 2013)
- EPs export clinical quality data to CMS (or Medicare intermediary), assuming that HHS has the capability to receive data

- Provide feedback to CMS, EHR vendor, and measure developers regarding data export

To support the above proposed approach, we are providing detailed examples below to highlight the current realities of capturing clinical quality measure using EHRs. We also are providing recommendations for clarification and improvements to the proposed clinical quality measure reporting criteria.

Attestation

CMS' rule proposes that physicians use an attestation methodology to submit summary information (numerators, denominators, and exceptions) to CMS on clinical quality measures as a condition of demonstrating meaningful use of certified EHR technology in 2011. We support the fact that CMS includes exceptions in the type of information that an EP will be required to include in the report sent to CMS. Exceptions are a critical component of measure results, demonstrating important variation in care (e.g., explanations for why patients who are included in the denominator population did not receive a process or outcome of care (described in the numerator) due to a patient reason (an allergy) or system reason (vaccine shortage)). However, it is unclear from the limited information included in the proposed rule how attestation will be operationalized. Details must be provided on how physicians would ultimately communicate this summary of clinical quality information to CMS. For example, how soon after the end of a reporting period will an EP be required to submit the summary information on the clinical quality measures? We encourage CMS to allow sufficient time, no less than three months following the end of a reporting period, for the summary of eligible patients to be generated. The complexity of generating this type of summary report should not be underestimated—in particular for a practice that has recently purchased and implemented an EHR. For this reason, a streamlined attestation policy must be simplified in initial program years, and the submission of an attestation report should not be required until Stage 1, Year 2 (2012). In addition, EPs should be able to provide their attestation through several modalities including email, phone, or snail mail. The burden of proof should be limited, and those on the front lines of health care should be able to focus on how the functionality provided through use of an adopted EHR can improve workflow and quality. The goal should not be compliance for compliance sake, but helping physicians understand and use EHRs to improve care.

We recommend that attestation for using EHRs to capture clinical quality measures be streamlined with other attestation requirements outlined in the proposed rule, such as use of EHRs to report HIT functionality measures. Another aspect that is unclear is the reference in the Standards and Certification Interim Final Rule issued by ONC. Table 2A communicates that the CMS PQRI 2008 Registry XML specification will be the format by which quality measure information should be transmitted. This conflicts with the proposal that EPs will "attest" to meaningful use of EHR in 2011. We ask that the agency clarify these statements. It is explained that Medicaid providers will qualify for incentive payments by adopting, implementing, or upgrading to certified EHR technology, and therefore will not need to attest to meaningful use of EHRs in 2011.

Although we recognize the need for varying thresholds, the agency should explain this variability within attestation requirements.

We recommend that physicians <u>not</u> be required to report to CMS or the states any clinical quality measure summary information in the initial program year, but rather use the first year to become familiar with the clinical quality measures and specifications, and begin to enter the required data for quality reporting into the EHR system. This will ensure that in the Stage 1, Year 2, when the EP prepares the summary report of measure results that the data will actually be there. If specifications are not tested, the information generated from using EHRs to report on clinical quality measures could be inaccurate. Testing the EHR specifications for the measures first is critical to ensure accurate quality measure reporting and meaningful quality improvement. If the agency firmly believes that "measurement and acting on the results of such measurement is an important aspect to improving quality," then testing to ensure accurate capture of quality measures is essential.

Certain statutory limitations apply to the reporting of clinical quality measures, such as prohibiting the Secretary from requiring the electronic reporting of information on clinical quality measures unless the Secretary has the capacity to accept the information electronically. We agree with these statutory limitations, but also question whether the Secretary has the current systems and staff in place to accept and analyze accurate summary clinical information (e.g., numerator, denominator, and exception data). Since the inception of the Physician's Quality Reporting Initiative (PQRI) under CMS, a significant amount has been learned about the importance of quality measure development and reporting. We should recognize the importance of establishing incentive program reporting requirements within a capable government framework that are broad-based and achievable to encourage the widest possible adoption.

For 2012, CMS proposes that an attestation would no longer be acceptable, and physicians would need to electronically submit quality reporting information. This is too aggressive of a timeline, and instead of required electronic submission in 2012, the agency should build in flexibility based on lessons learned from 2011 implementation. **Accurate and consistent data capture must happen first before external reporting, as reflected in our proposed revised stages for clinical quality measure reporting.**

We support that clinical quality measure reporting include denominators, numerators, *and exceptions*, which provide critical information on variations in care. Therefore, for 2010 EPs should only be required to download Level I specifications for three clinically relevant measures, and Level II specifications should be made available to EHR vendors, Health Information Exchanges, and registries. Testing of these specifications should be completed at two different levels: 1) in a true test system environment (not a live EHR) using "dummy" patient data developed with the sole purpose of testing the measure logic; and 2) testing in a live clinical environment, within a live EHR system with actual patient clinical information. The results generated from evaluating and testing these specifications will allow necessary refinements to measure

specifications, but these two levels of testing require significant time and resources to be completed.

Timeline of EHR Incentive Program Implementation with Software Development Cycles

CMS recognizes in the proposed regulation that some measures are further developed than others and it therefore, does not intend to finalize those measures without complete specifications during its proposed timeframe. However, the agency implies that sufficient time does exist to complete work on measures and measures specifications to allow vendors, EPs, and eligible hospitals to implement such systems by 2011. We disagree. If a certain data element required for a measure is not captured within an EHR, that product will require a system level change. **We do not believe that the approximately 17 months from the time the final rule will be published to the latest date when an EP can begin reporting in 2011 to meet the 90-day reporting requirement is sufficient time to perform and test these system level changes.** There is not enough time for vendors to develop, test, and distribute systems to include EHR system releases and for their customers—EPs and hospitals—to implement the new version of the software and complete the technology life cycle, which includes but is not limited to requirements, implementation, testing, and rollout. For this reason, our recommendation of segmenting Stage 1 into Year 1 (2011) and Year 2 (2012) will give the EPs and EHR vendors the additional time needed to ensure that data elements required for clinical quality measures are captureable in the EHR systems. This segmentation of Stage 1 will also allow time for the EPs and EHR vendors to provide feedback to CMS and the measure developers on the format and usability of the EHR specifications for clinical quality measures.

Measures

For physicians interested in attaining meaningful user status to qualify for the incentive payments, CMS proposes that EPs will need to report on both core clinical quality measures and applicable measures in a defined specialty measure group. This proposal does not however, take into account whether all of the measures and specifications apply equally to every physician. **We are concerned that a "one-size fits all approach" will require all specialties to comply with measures and specifications that may be irrelevant for them, and further does not move the needle on quality improvement.** For example, reporting blood pressure measurement (a listed core measure) is not something typically done by a dermatologist. Flexibility must be exercised on how EPs satisfy the clinical quality measure reporting requirements of meaningful use, as not all specialties and provider types currently have quality measures specified, tested and endorsed for capture under an EHR.

We recommend the core measures (listed in Table 4 in the proposed rule) be dissolved and that these measures related to preventive care and screening regarding tobacco use, blood pressure measurement, and drugs to be avoided in the elderly be moved to the primary care specialty group. We recommend that EPs be

able to attest that they have selected at least three clinically relevant quality measures (if applicable); have downloaded and reviewed the Level 1 (human readable) measure specifications for these measures; are entering the data required for these measures into their EHR system to the best of their ability; are providing feedback to the EHR vendor where structured data fields are not available; and are reporting to CMS (and appropriate measure developer(s)) any concerns/issues with measure specifications. Recommending selection of at least three measures is consistent with program requirements under the CMS PQRI program.

Like PQRI, if three clinically relevant measures cannot be identified among the specialty group(s), the EP should be able to attest that zero, one or two measures from the total list of proposed quality measures for the meaningful use program are applicable. The EP would then download the specifications for applicable program measures in 2011. In addition, those EPs who elect the EHR reporting option under the CMS PQRI program should automatically satisfy the clinical measure reporting requirements for meaningful use in 2011.

Measure Readiness

Specifying the measures for implementation in an EHR is a detailed process that requires the development of Level I specifications – human readable format, and Level II specifications – the transition of human readable to the HL7 Draft Standard for Trial Use (DSTU) eMeasure. Significant progress has been made in developing the Level I EHR Specifications for the proposed measures for the EHR incentive program. While plans are in place to have the eMeasure specifications for 20 of the PCPI measures listed in the proposed rule, we caution the agency against requiring these eMeasure specifications be used in the first year, as the eMeasure standard represents a newly established DSTU that has not yet been tested in EHR systems. Failure to allow sufficient time for testing will prevent physicians from the opportunity to successfully measure and identify areas for quality improvement. The Level I EHR Specifications can be used to begin to orient the EP and the EHR vendor with the requirements for data capture and reporting on clinical quality measures in Stage 1, Year 1. This additional year will allow EHR Vendors to test whether the eMeasure standard can be integrated into their systems.

Efforts are underway by the AMA-convened Physician Consortium for Performance Improvement (AMA-PCPI) to develop Level I EHR Specifications for its quality measures included in the proposed rule – this work includes testing and is being done in partnership with relevant medical specialty societies. The AMA is working closely with the EHR vendor community and others to increase functionality in EHR systems that facilitate physician use of measures for quality improvement and reporting. The AMA, with the National Committee for Quality Assurance (NCQA), and the Health Information Management Systems Society's Electronic Health Record Association, continue to cosponsor the Collaborative for Performance Measurement Integration with EHR systems (Collaborative). The Collaborative is focused on facilitating the integration of performance measures into EHR systems to enable accurate translation of measures and to promote quality improvement. Procedural protections are needed, however, to ensure

physicians and other clinicians can successfully submit data to a federal agency from an EHR product.

The proposed regulation also fails to mention the importance of testing clinical quality measures specified for EHRs as a data source. As demonstrated through an Agency for Health Care Research and Quality (AHRQ) funded AMA project entitled "Cardio HIT," testing EHR specifications across varying practice sites using different HIT software is invaluable. The six practice sites involved in CARDIO-HIT had already purchased and been using their EHR for at least four years before participating in the use of their EHR to capture quality measures related to Coronary Artery Disease and Heart Failure. Automatic querying and reporting was not fully accurate for every measure, and as a result modifications were made along the way to make improvements to the how the measures were captured within the varying EHR systems used in the six sites. Moreover, each practice site had one dedicated physician and one HIT expert to oversee integration of quality measures within their EHRs. This work proved to be quite involved and time consuming for these very experienced practice sites; it should not be assumed that new users of EHR systems will be able to report on clinical quality measures on day one.

Measures Development

The proposed rule states that the agency does not believe there needs to be any special restriction on who can develop measures. We disagree. Physicians must develop the quality measures used for collecting and reporting data. This ensures that the measures are accurate and clinically relevant to patients.

In 2000, the AMA convened the PCPI to develop clinical performance measures that are patient-focused and that can be implemented to improve patient outcomes. The PCPI actively engages all stakeholders including payers, patient advocates and other organizations that are committed to high quality care. The PCPI is comprised of over 170 member organizations, including: national medical specialty and state medical societies; other health care professional organizations; the Council of Medical Specialty Societies; American Board of Medical Specialties and its member-boards; experts in methodology and data collection; the Agency for Healthcare Research and Quality; and CMS.

As the leading developer of physician-level measures, we urge that the PCPI be recognized as such in CMS' plan to ensure that clinically relevant quality measures are accurately specified and adequately testing for inclusion in the meaningful use program. The PCPI incorporates all critical factors in the measure development process and is also committed to maintaining its portfolio of measures. It operates through a transparent, consensus-based process for developing physician-level measures, and has worked aggressively in developing to date more than 250 physician performance measures and specifications covering 40 clinical topics and conditions. These measures are available for implementation and many have been adopted by CMS for use in CMS quality improvement demonstration projects and the PQRI. **In addition, the PCPI ensures that measures: (i) are evidence based and developed with cross-specialty representation and consensus; (ii) include enhanced relevance to clinical practice; and (iii) that the**

measure developer is committed to maintaining its measures. Any incentive program must use measures that meet these criteria.

Endorsement

The proposed rule states that "preference" will be given to National Quality Forum (NQF) endorsed measures for inclusion in the meaningful use program. We agree with the provision allowed by the Secretary to consider non-NQF endorsed measures for the EHR Incentive Program. However, endorsement work should not be undertaken by another entity during this time. All clinical quality measures should eventually go through the NQF endorsement process. **We recommend measures included in the proposed incentive program that did not have NQF endorsement at the onset, be submitted for endorsement by NQF within a certain timeframe (e.g., 12-18 months).** The manner in which NQF reviews measures (e.g., by project, frequently covering a single clinical area) should be taken into consideration when establishing an appropriate timeframe for review.

Publication of EHR Specifications for Clinical Quality Measures

The proposed rule is not clear as to when EHR specifications for EP clinical quality measures will be posted on the CMS website. It states that 2011 specifications for user submission for clinical quality measures will be available when they are sufficiently developed or finalized. However, it then states that CMS is targeting finalization and publication of detailed specifications documents for all 2011 payment year clinical quality measures for "eligible hospitals" on the CMS website on or before April 1, 2010. Recognizing that only a handful of the specifications for the proposed EP clinical quality measures will be developed at the time the final rule is posted, it is not feasible to say that final specifications will be posted at least nine months prior to January 1, 2011. Our recommendations to segment the Stage 1 requirements into two years—downloading Level 1 specifications for entering data elements in 2011 and producing a summary of measure results in 2012—provides a more realistic timeframe to download and test the EHR specifications, which enables EPs to better utilize their EHR to accurately report on clinical quality measures. Therefore, the timelines for posting specifications must be pushed back, and the scope of what physicians are required to report on to fulfill meaningful use for clinical quality measure reporting must be more realistic. We recommend that physicians only report on three clinical quality measures when applicable, or attest that less than three measures are applicable in 2011. Providing another 12 months for EHR specification development and testing will promote improved physician buy-in at the onset of the program.

Harmonization of Specifications Across Quality Reporting Programs

Specifications for EHR Quality Reporting programs must be harmonized across various government programs. We appreciate recognition in the proposed rule that duplicate reporting be avoided across Medicare quality reporting programs to the extent practicable. However, the regulation does not stipulate that the measures included in the

EHR meaningful use and PQRI programs be harmonized. It only states that allowing an EHR reporting mechanism for the PQRI and the Reporting Hospital Quality Data for Annual Payment Update Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) programs would provide an added incentive for physicians to adopt EHRs. It will be burdensome for a physician who participates in PQRI through the EHR reporting mechanism to also report on a slightly different clinical measure in the EHR incentive program. The agency should work to not only encourage use of EHR reporting mechanisms within the PQRI and RHQDAPU programs, but also harmonize the EHR specifications and measures across programs.

If HHS proceeds with a regulation that strictly ties the ARRA incentives to quality benchmarks, requires compliance with measures not applicable to all specialties, and fails to take into account that specifications for the proposed measures for the EHR Incentive Program have not been adequately tested, our collective goal of widespread health IT adoption and quality improvement at the point of care will be seriously compromised. As articulated above, we strongly urge the agency to revise the meaningful use criteria for using EHRs to capture clinical quality measures.

EP Objective 13: *Send reminders to patients per patient preference for preventive/follow-up care.*
EP Measure 13: *Reminder sent to at least 50 percent of all unique patients seen by the EP that are 50 and over.*
Recommendation on Objective and Measure 13: *Remove per patient preference. Remove 50 percent threshold requirement from Stage 1. EPs should only have to attest to sending reminders to patients.*

In general, we support CMS' proposed objective for sending reminders for preventive/follow-up care. Although we support EPs utilizing this electronic capability as part of their daily work process, we believe that for Stage 1, EPs should have the discretion to issue reminders in a variety of ways. Under the current system, physicians deploy multiple methods for issuing patient reminders. For Stage 1, the proposed measure should be flexible enough to allow for reminders to be provided via phone calls, voice mail messages, emails, printed reminder notice provided after the initial visit, etc. For clinicians who manage sensitive conditions such as mental health, a larger percentage of their patients may request that no reminders (such as phone calls or mailed cards) be sent. Physicians should have the flexibility during Stage 1 to implement method(s) that work best for the physician practice and the patient. The proposed denominator would be difficult to capture since many physicians use their practice management system (PMS) to track appointments and not their EHR. It would also be extremely burdensome for a physician to track how many phone calls were made, letters mailed, emails were sent, etc. Costly interfaces between the PMS and EHR systems would need to be created to allow the tracking of and sending of reminders through the use of EHRs. Furthermore, physicians should have the flexibility to determine if they want to meet this requirement by sending reminders to patients under 50 years of age, particularly for those serving Medicaid patients. **We propose that CMS eliminate the**

numerator and denominator requirement and only require EPs to attest that they send reminders to patients.

EP Objective 14: *Implement five clinical decision support rules relevant to specialty or high clinical priority, including for diagnostic test ordering, along with the ability to track compliance with those rules.*
EP Measure 14: *Implement five clinical decision support rules relevant to the clinical quality metrics the EP is responsible for.*
Recommendation: *Implement one clinical decision support rule relevant to the clinical quality metrics the EP is responsible for.*

We do not support CMS' proposed measure to require EPs to implement five clinical decision support rules relevant to the clinical quality metrics the EP is responsible for during Stage 1. The financial and staff resources associated with customizing these forms and tools must be taken into consideration before requiring a threshold of five clinical decision support rules be implemented in 2011. In order to develop appropriate rules, it must be derived from scientific evidence, much like measure development, and consensus. Once the clinical decision support rules are created they then need to be incorporated into EHRs, which takes time for vendors to implement and physician offices to understand. We also seek clarification from CMS on whether modifying an EHR clinical decision support tool to meet a practice's needs would in any way negate EHR certification. **EPs should only have to attest to implementing at least 1 clinical decision support rule during the reporting period.**

EP Objective 15: *Check insurance eligibility electronically from public and private payers.*
EP Measure 15: *Insurance eligibility checked electronically for at least 80 percent of all unique patients seen by the EP.*
Recommendation 15: *Remove from Stage 1.*

AND

EP Objective 16: *Submit claims electronically to public and private payers.*
EP Measure 16: *At least 80 percent of all claims filed electronically by the EP.*
Recommendation 16: *Remove from Stage 1.*

We strongly disagree with CMS' proposed objectives and measures to require an EP to attest to checking insurance eligibility electronically and submitting claims electronically to public and private payers, and we recommend their removal from Stage 1 meaningful use criteria. We believe conducting eligibility and claims submission are purely practice management functions performed by administrative staff, not clinicians. Generally, checking eligibility is a function physicians perform through their practice management system (PMS), not their EHR. It is therefore, unclear how checking eligibility and submitting claims electronically are intended to increase or improve a physician's use of their EHR. Moreover, these measures would require electronic interfaces, which are very costly. We believe that these proposed measures are

outside the scope of the EHR incentive programs, and will distract from other incentive objectives and measures that are aimed at improving the quality and efficiency of care and accelerating physician adoption and use of EHRs.

Most physicians' practice management systems are separate from their EHR systems. To check insurance eligibility per patient, most physician practices have to go to the payer's website or call the payer to get this information. In addition, many physicians have confirmed eligibility on-line with private payers but end up with a denied claim later because the patient had reached maximum benefits on a particular service. As for Medicare patients, there is no widely available electronic eligibility capability, and so physicians have to call Medicare to check on eligibility, which is a time-consuming process. Most clearinghouses used by physicians do not provide real-time eligibility checking, but rather a batch style checking done 24 hours in advance.

Physicians also do not find the current eligibility standard helpful, therefore, they are forced to conduct this process manually often after attempting it electronically. The information that is typically returned when a payer does respond is sufficiently vague or incomplete as to warrant it meaningless in many cases. Most payers respond with a simple "yes" or "no" which is of limited value to the physician because it only tells the physician that the patient is covered; it does not tell the physician if the patient is covered for a particular service. According to Emdeon, one of the nation's largest clearinghouses, only 60 percent of eligibility transactions are conducted electronically. It is hard to understand the rationale for requiring physicians to conduct a transaction that does not give them the information they need.

For some physicians, checking eligibility for each patient also may not be worth the time spent since claims reimbursement for payers is so low. If this requirement is adopted, physicians will be unfairly asked to incur additional administrative expense, typically around 25 cents per eligibility standard transaction for each patient - regardless if the patient is new or established - when the response will not provide helpful information to the physician because: 1) a number of payers still do not offer electronic eligibility verification; 2) a number of payers that offer electronic verification only provide the most basic information which is not very helpful; and 3) payers do not guarantee their eligibility results. Thus, at 25 cents per electronic verification, the typical primary care doctor would be required to spend $2000 per year (assuming 8000 visits) for little if no return. Administrators of practices that have a high Medicare patient population and mainly a Medicare FFS (not including Medicate Advantage or HMO) patient base, indicated they find little value in eligibility verification. Medicare patients have a fixed benefit level that is standardized and primary care services are limited without the need for pre-authorization. In the case of this type of medical practice, requiring electronic eligibility verification will be an administrative burden and additional expense without a clear benefit.

In addition, while CMS views PMS as a type of EHR module, it is important to note that there is no PMS certification process in effect today. **We are concerned that ONC has elected to include PMS as a portion of the EHR certification process when there is**

still no agreed upon set of criteria for these systems. Organized medicine is working on developing a list of proposed criteria and are eager to work with PMS vendors and other stakeholders on arriving at an agreed upon set of standards. Moreover, this would require electronic interfaces, which are very costly.

We also do not believe that CMS should include a requirement for checking eligibility electronically as part of the EHR incentive program criteria when many payers are still not in compliance with the HIPAA 270/271 electronic eligibility standard. This standard has been in effect since October 2004 even for small health plans. We are also concerned that CMS has tied the EHR incentive payments to eligibility during Stage 1 which will coincide with the industry's transition to the next version of HIPAA standards, version 5010. We expect just as with past HIPAA implementations, there will be implementation barriers physicians will need to overcome, many of which could be outside their control. According to an analysis published in *Health Affairs* ("What Does it Cost Physician Practices to Interact With Health Insurance Plans?," May 14, 2009, web exclusive), an estimated $31 billion dollars ($69,274 per practice) is spent annually by physicians interacting with health plans. Much of these costs could be avoided if compliance with HIPAA transactions and code sets was enforced. **It is incumbent upon CMS to require all payers to comply with the HIPAA transactions and code sets requirements that have been required for use by the industry for almost six years, prior to establishing any requirement for physicians' use that is tied to EHR incentives.**

Like the requirement to check eligibility electronically, requiring most claims be submitted electronically is a PMS function, not an EHR function. PMS systems are represented by an ecology of vendors separate from EHRs and none of these systems are certified today. There is also no agreed up certification standards for practice management systems. EHR software programmers also typically do not have the expertise to efficiently add these administrative functions into the clinical EHR workflow. Moreover, this would require electronic interfaces, which are very costly. Requiring EHRs to add claims submission to its functionality on top of the other required EHR system functions only raises increased administrative expense to physicians and inefficient EHR functionality.

As for electronic claims submissions, we are unclear how CMS envisions claims would be sent electronically and would appreciate clarification of how physicians can submit claims electronically, under this requirement. At this point in time, there are many claim submission processes in place, due to the payers non-compliance with HIPAA. Some payers require physicians to submit electronic claims through their clearinghouses and are unwilling to provide a direct connection as required under HIPAA. Some payers do not accept electronic claims and therefore clearinghouses are required to drop an electronic claim to paper. Physicians currently submit claims through practice management systems, billing services or clearinghouses. The proposed rule is unclear as to whether the proposed objective and measure will allow physicians to continue to submit their claims through the above-mentioned options. Similar to our concerns with payer non-compliance with eligibility transactions, payers are also frequently out of compliance with the HIPAA claim transaction standard, concerns we have already shared

with CMS. **We do not believe CMS should impose additional claims submission requirements on physicians until the vast majority of payers are in compliance with the HIPAA electronic transactions.** We appreciate the Administration's desire for increased administrative simplification and believe that addressing problems associated with accurate, real-time eligibility information and electronic claims submissions separately will result in greater efficiencies for physicians and payers. We would also note that under the Administrative Simplification Compliance Act (ASCA), practices with 10 or fewer FTEs are not required by law to bill electronically and this requirement does not address this exemption.

EP Objective 17: *Provide patients with an electronic copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.*
EP Measure 17: *At least 80 percent of all patients who request an electronic copy of their health information are provided it within 48 hours.*

AND

EP Objective 18: *Provide patients with timely electronic access to their health information (including lab results, problem list, medication lists, allergies) within 96 hours of the information being available to the EP.*
EP Measure 18: *At least 10 percent of all unique patients seen by the EP are provided timely electronic access to their health information.*

AND

EP Objective 19: *Provide clinical summaries to patients for each office visit.*
EP Measure 19: *Clinical summaries provided to patients for at least 80 percent of all office visits.*

Recommendation: *The above-mentioned objectives and measures (17-19) should be combined into one objective and measure to state:*
EP Objective: *Provide patients with an electronic or printed copy of their health information (including diagnostic test results, problem list, medication lists, and allergies) upon request.*
EP Measure: *All patients who request an electronic copy of their health information are provided either an electronic or printed copy within a reasonable period of time in accordance with federal and/or state law.*

Although we support CMS' proposed objectives to provide patients with an electronic copy of their health information upon request, we strongly oppose CMS' proposed measure for Stage 1 that requires physicians to provide only electronic copies, within 48 hours and to provide patients access to their health information within 96 hours of when it is available to the physician. We strongly recommend that for Stage 1, EPs have the flexibility to provide either an electronic or paper copy generated by the EHR within the time period allowed under HIPAA. It is important to

keep in mind that interfaces with EHRs and patient portals (e.g., patient logs on and can access test results online) are not readily available and will be costly to implement. This will create an additional expense for physicians because they will need to purchase this capacity and associated technical support. The implementation time associated with developing a patient portal is also very long. Any requirement that exceeds printing should not be mandated for Stage 1, including the proposed abbreviated turn around time of 48/96 hours, which exceeds the amount of time permitted under HIPAA for providing patients with a copy of their health information (HIPAA requires providing a patient access to their medical information within 30 days from the date of the patient's request, and also authorizes an extension period up to an additional 30 days).

It is also important to keep in mind that physicians already adhere to communication standards of medical information to patients (e.g., must be timely, which depends on criticality of information; urgency of need to know and urgency of need to act on this knowledge, personal communication for difficult information). All communication depends on physician's knowledge of the patient, how the patient will accept information, the impact of information, etc. Physicians should have the discretion to make these determinations based on the physician-patient relationship.

Physicians and patients are in the best position to determine what records are needed and when they are needed. Physicians should also have the discretion to discuss test results with their patients prior to sharing them with patients. Patients could receive information that is confusing or unanticipated lab results (e.g., confusion over medical terminology to describe results or diagnostic tests indicating poor prognosis) that may cause undue anxiety if the clinician does not have sufficient opportunity to clarify results with their patients.

As for clinical summaries, physicians need ample time to complete a clinical summary after a patient visit, collect and review relevant health care information, including test results, discuss results with patient, if appropriate, prior to providing a patient with a summary. As previously mentioned, physicians and patients are in the best position to determine what records are needed and when they are needed. It may not be practical or necessary for a physician to give every patient a clinical summary of the visit right at the end of a visit. **Therefore, we urge CMS to combine the above-mentioned objectives and measures (17-19) into a single objective and measure for Stage 1 that calls for, "All patients who request an electronic copy of their health information are provided either an electronic or printed copy within a reasonable period of time in accordance with federal and/or state law."**

EP Objective 20: *Capability to exchange key clinical information (for example, problem list, medication list, allergies, and diagnostic test results), among providers of care and patient authorized entities electronically.*
EP Measure 20: *Performed at least one test of certified EHR technology's capacity to electronically exchange key clinical information.*
Recommendation 20: *Remove from Stage 1.*

We do not support CMS' proposed objective and measure to have each EP test his/her certified EHR technology's capacity to electronically exchange key clinical information during Stage 1. CMS recognizes in the proposed rule that in most areas of the country, the infrastructure necessary to support such exchange is not yet currently available. Rather than requiring each EP to test interoperability, we strongly recommend that CMS pursue pilot programs or testing solutions for improving health information exchanges needed for supporting the incentive programs.

EP Objective 21: *Perform medication reconciliation at relevant encounters and each transition of care.*
EP Measure 21: *Perform medication reconciliation for at least 80 percent of relevant encounters and transitions of care.*
Recommendation 21: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to attest that they perform medication reconciliation.*

Although we strongly support medication reconciliation support, we do not support CMS' proposed 80 percent threshold requirement for Stage 1. The essence of medication reconciliation is making sense of a patient's medications and resolving conflicts between different sources of information to minimize harm and maximize therapeutic effects. It is an ongoing, dynamic, episodic and team-based process that should be led by and is the responsibility of the patient's attending/personal physician in collaboration with other health care professionals. Medication reconciliation is essential to optimize the safe and effective use of medications. It is one element in the process of therapeutic use of medications and medication management for which physicians are ultimately held legally accountable. CMS should clearly define the terms, "relevant encounter" and "transition of care." As we mentioned previously, the manually capturing of numerators and denominators will be extremely burdensome absent EHR automatic tracking and reporting functionalities. The denominator for this objective is the number of relevant encounters and transitions of care for which the EP was a participant during the EHR reporting period, which will require manual calculations. **For Stage 1, EPs should only have to attest that they perform medication reconciliation.**

EP Objective 22: *Provide summary care record for each transition of care and referral.*
EP Measure 22: *Provide summary of care record for at least 80 percent of transitions of care and referrals.*
Recommendation 22: *Remove 80 percent threshold requirement from Stage 1. EPs should only have to attest to providing summary care records for transitions of care and referrals when requested.*

We support providing a summary care record for each transition of care and referral only upon request and do not support the 80 percent threshold requirement for Stage 1. We recommend that CMS provide a clear definition for the summary of care for the ambulatory setting. The denominator for this objective is the number of transitions of care for which the EP was the transferring or referring provider during the EHR reporting period. As we mentioned previously, the manually capturing of numerators and denominators will be extremely burdensome absent EHR automatic

tracking and reporting capabilities. **For Stage 1, EPs should only have to attest to providing summary care records for transitions of care and referrals when requested by patients, in lieu of the 80 percent threshold.**

EP Objective 23: *Capability to submit electronic data to immunization registries and actual submission where required and accepted.*
EP Measure 23: *Performed at least one test of certified EHR technology's capacity to submit electronic data to immunization registries.*
Recommendation: *Remove from Stage 1.*

AND

EP Objective 24: *Capability to provide electronic syndromic surveillance data to public health agencies and actual transmission according to applicable law and practice.*
EP Measure 24: *Performed at least one test of certified EHR technology's capacity to provide electronic syndromic surveillance data to public health agencies (unless none of the public health agencies to which an EP submits such information have the capacity to receive the information electronically).*
Recommendation: *Remove from Stage 1.*

We do not support CMS' proposed objective and measure to require EPs to perform at least one test of their EHR's capacity to submit electronic data to immunization registries or to provide electronic syndromic surveillance data to public health agencies during Stage 1. Interfaces with immunization registries and public health agencies do not readily exist. This objective is not relevant to all specialties. We recommend that CMS postpone these objectives and measures until interfaces readily exist for this type of data submission. More time is needed to test these objectives (23-24) to ensure their readiness so they should be removed from Stage 1.

EP Objective 25: *Protect electronic health information maintained using certified EHR technology through the implementation of appropriate technical capabilities.*
EP Measure 25: *Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308 (a)(1) and implement security updates as necessary.*
Recommendation: *We support this measure.*

We strongly support this measure to conduct or review a security risk analysis in accordance with the HIPAA Security Rule. We are, however, concerned that physicians will not be well positioned to determine whether they are using the "appropriate technical capabilities." Therefore, we believe it is necessary for CMS to require vendors or make directly available resources to physicians to help them identify the specific technical capabilities they will need to ensure patient information is appropriately protected and safeguarded.

Other objectives and measures that were under consideration for EPs

We agree with CMS' decision to not include all objectives and measures recommended by the Health IT Policy Committee given our concerns over the volume of objectives and measures for the initial phase of meaningful use of EHRs (Stage 1). We do believe that these advance directives, documenting a progress note, and providing patient-specific education resources upon request are important objectives and should be considered for later Stages.

Requirements specific to the Medicaid program

Given the significant level of interaction between the Medicare and Medicaid programs, we agree with CMS' proposal to create a common definition of meaningful use that would apply for providers participating in the Medicare Fee For Service (FFS), Medicare Advantage (MA) EHR incentive programs through Medicare Advantage Organizations, and for eligible providers participating in the Medicaid EHR incentive program. We urge States to only consider additional objectives and measures that do not conflict with the Medicare meaningful use requirements, and those that do not create additional burdens on providers seeking Medicaid incentive payments. To determine patient volumes under the Medicaid incentive program, we recommend that CMS consider a time period involving patient encounters that would maximize EP eligibility.

Conclusion

Encouraging physician adoption of Health IT, especially small physician practices, is critical to ensuring widespread EHR use. Unrealistic timelines and criteria will only serve to undermine this effort. We are deeply committed to significantly increasing EHR adoption and ensuring that all eligible practices, especially smaller practices, are able to take advantage of the stimulus funds. **We believe Stage 1 should be redefined and the proposed criteria should be segmented into two years to provide more flexibility on functionality measures and selection/awareness of quality measures as follows:**

Stage 1-First Payment Year. 1) EPs should only be required to attest to meeting at least five of the health IT measures as described above, including the proposed requirement to maintain an up-to-date problem list. 2) EPs should only have to attest that they have selected three clinically relevant quality measures, if appropriate, and have downloaded and reviewed the Level 1 (human readable) measure specifications for these measures. The attestation should only require EPs to attest that, to the best of their ability, they are: entering the required data elements for quality measure reporting where those fields exist in the EHR; providing feedback to the EHR vendor where structured data fields are not available; and reporting to CMS and the appropriate measure developer any concerns/issues with EHR specifications. For those EPs unable to identify three clinically relevant measures with Level 1 measure specifications *adopted* under the incentive programs, they would attest that less than three or none apply for 2011.

Stage 1-Second Payment Year. 1) EPs should only be required to attest to meeting at least five health IT measures. 2) EPs should only have to attest that their EHR system has produced an automated report providing aggregate performance information (e.g.,

numerators, denominators, exceptions) for all patients for which the clinical quality measures they selected in Stage 1 apply, and they report to CMS (as well as measure developers) any identified issues with accuracy and completeness.

We are hopeful that we can work with the Administration to finalize regulations that truly foster EHR adoption and participation in the EHR incentive programs. 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 Family Physicians
American Academy of Home Care Physicians
American Academy of Neurology Professional Association
American Academy of Ophthalmology
American Academy of Otolaryngology – Head and Neck Surgery
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Academy of Sleep Medicine
American Association of Clinical Endocrinologists
American College of Cardiology
American College of Chest Physicians
American College of Gastroenterology
American College of Obstetricians and Gynecologists
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Osteopathic Surgeons
American Academy of Pediatrics
American College of Physicians
American College of Radiation Oncology
American College of Rheumatology
American College of Surgeons
American Gastroenterological Association
American Geriatrics Society
American Medical Association
American Osteopathic Academy of Orthopedics
American Osteopathic Association
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 Clinical Oncology
American Society of Hematology
American Society of Nephrology

American Society of Plastic Surgeons
American Thoracic Society
American Urological Association
Heart Rhythm Society
Infectious Diseases Society of America
Joint Council of Allergy, Asthma and Immunology
Medical Group Management Association
North American Spine Society
Renal Physicians Association
Society for Cardiovascular Angiography and Interventions
Society for Vascular Surgery
Society of Hospital Medicine
The Endocrine Society

Medical Association of the State of Alabama
Alaska State Medical Association
Arizona Medical Association
Arkansas Medical Society
California Medical Association
Colorado Medical Society
Connecticut State Medical Society
Medical Society of Delaware
Medical Society of the District of Columbia
Florida Medical Association, Inc.
Medical Association of Georgia
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
Michigan State Medical Society
Minnesota Medical Association
Mississippi State Medical Association
Missouri State Medical Association
Montana Medical Association
Nevada State Medical Association
New Hampshire Medical Society
Medical Society of New Jersey
New Mexico Medical Society
Medical Society of the State of New York

North Carolina Medical Society
North Dakota Medical Association
Ohio State Medical Association
Oklahoma State Medical Association
Oregon Medical Association
Pennsylvania Medical Society
Rhode Island Medical Society
South Carolina Medical Association
South Dakota State Medical Association
Utah Medical Association
Wisconsin Medical Society
Vermont Medical Society
Medical Society of Virginia
Washington State Medical Association
West Virginia State Medical Association
Wyoming Medical Society