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National Coordinator
Health Information Technology
Office of the National Coordinator for Health
Information Technology
Health IT Policy Committee
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: Health Information Technology; HIT Policy Committee: Request for Comment Regarding the Stage 3 Definition of Meaningful Use of Electronic Health Records

Dear Dr. Mostashari:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Health IT Policy Committee's proposal for Stage 3 of the Medicare/Medicaid meaningful use Electronic Health Record (EHR) Program. The meaningful use program has helped to jump start EHR use, but we are still in the early stage of progress due to technological, financial, operational, and regulatory challenges. These challenges must be overcome in order to increase physician participation rates and maximize the benefits of this technology for our nation's health care delivery system. **While the AMA shares the Administration's goal of widespread EHR adoption and use, we are extremely concerned with the recommended approach to move full speed ahead without a comprehensive evaluation of the program and resolving existing barriers, including Health IT infrastructure flaws.**

Overall Concerns and Recommendations for Improving the Meaningful Use Program

The top five concerns and recommendations we continue to hear from physicians are as follows:

1. **100 percent pass rate is not the right approach.** The current and future meaningful use requirements are problematic, given that failing to meet just one measure by one percent would make a physician ineligible for incentives and subject to financial

penalties. The measures for use of EHRs should be made reasonable and achievable and still have a meaningful impact.

2. **One size does not fit all.** Under the current program, every physician regardless of their specialty must meet the same measures (i.e., core measures), and there are few exceptions. The program requirements should be appropriately flexible and better structured to accommodate various practice patterns and specialties. Also, additional resources and time to develop and test e-specified electronic measures focused on outcomes must be allotted to ensure successful implementation of the meaningful use program.

3. **Evaluation process is lacking and essential to improving the program.** The Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) have not evaluated the meaningful use program. Given the concerns raised with the current program, an external, independent evaluation is necessary to improve and inform the future of the program.

4. **Usability of certified EHRs should be addressed.** More and more physicians are raising concerns regarding the usability of EHRs. More attention needs to be paid during the EHR certification process to address physician usability concerns.

5. **Health IT infrastructure barriers should be resolved.** The Health IT infrastructure does not enable physicians to readily share patient data electronically with other health care providers, which is essential for improving the value and efficiency of our health care delivery system. Improving the Health IT infrastructure to allow physicians to readily and securely exchange patient data with other health care providers should be made a top priority and take precedence over the development of future stages of the meaningful use program.

<u>100 Percent Pass Rate is Not the Right Approach</u>

Physicians should not have to meet all of the measures to be successful in the meaningful use program. For Stage 1, physicians have to meet a total of 15 core (required) measures, select five measures of their choice from a menu set of ten, and also meet six clinical quality measures. For Stage 2, physicians are required to meet more measures: 17 core measures, an additional three measures of their choice from a menu set of six measures, and starting in 2014, meet nine clinical quality measures. The Health IT Policy Committee's proposal for Stage 3 would nearly double the number of measures physicians would have to meet for each patient in order to avoid meaningful use financial penalties. Physicians are already experiencing hardships today trying to meet the high number of and percentage requirements for the meaningful use measures because there is no flexibility under the current program.

Failing to meet just one measure by one percent would make a physician ineligible for incentives and face the same financial penalties during the penalty phase as those physicians who make no effort to adopt EHRs. The AMA does not support the financial penalties associated with this program. At the very minimum, the Health IT Policy Committee should recommend that CMS follow the same regulatory approach for the meaningful use penalty program that they pursued with the Medicare e-prescribing and Physician Quality and Reporting System (PQRS) penalty programs by reducing the requirements for these programs during the penalty phase. For example, under the e-prescribing program, a physician is protected from a financial penalty if s/he transmits a prescription electronically ten times (as opposed to 25 times, which is required for an incentive). The pass rate for this program should be reasonable and achievable, especially in the penalty phase.

Recommendations:

1) **The meaningful use program should be modified to eliminate the regulatory requirement that physicians have to meet all of the measures, in order to be successful in the program.**

2) **During the penalty years, physicians should only have to meet ten of the meaningful use core/menu set of measures in order to avoid a financial penalty.**

<u>One Size Does Not Fit All</u>

The current meaningful use program requires all physicians, regardless of their specialty, patient population, geography, or practice size, to collect the same exact data on each and every patient for numerous measures even though the data may not be relevant to the patient's visit, service, or treatment. And, there are few exceptions to this "one size fits all" rule. No matter how high or low a percentage threshold is set for a particular measure, the Health IT Policy Committee, CMS, and ONC should keep in mind that there will be times during the reporting period (e.g., a full calendar year) when a physician will face barriers and not be able to meet the percentage thresholds for one or more of the required measures. Furthermore, it makes no sense to require specialists to meet measures that require the incorporation of additional, and at times, expensive functionalities into their EHRs, which they will rarely use for clinical practice. For example, some specialists order very few tests or submit data to immunization registries. Physicians should be able to invest in systems that make the most sense for their patients and their practice. While we are pleased that as of October 2012, a total of 124,564[1] physicians have been paid incentives under the

[1] http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Oct_IncentiveProgramPayment_Registration_SummaryReport.pdf

Medicare/Medicaid meaningful use program, we are concerned that the majority of eligible physicians have not yet registered or received incentives. According to CMS' data on specialists who have received Medicare incentives, physicians under the family practice and internal medicine categories are way ahead of other specialists when it comes to achieving meaningful use.[2] **This reinforces the concern we previously raised on the meaningful use program—the program's requirements are too rigid, primary-care focused, and lack the flexibility to accommodate specialists of all types.** We recommend that reasonable exclusions be built into every measure of the program so that a specialist can opt out of any measure if the measure has little relevance to the physician's routine scope of practice.

Given the challenges that physicians are facing with the meaningful use program, we also recommend that additional exemption categories be developed to protect more physicians from penalties. Exemptions should be available to physicians at or near retirement age, for small or rural physician practices that are facing challenges meeting meaningful use requirements, and for specialists who are unable to meet many of the measures due to their scope of practice. The program requirements should be modified and better structured to accommodate various practice patterns and specialties, and protect more physicians facing hardships from penalties.

Recommendations:

1) **All of the measures for meeting meaningful use should include exclusions and factor in relevancy.**

2) **Additional exemption categories to protect more physicians from penalties should also be established including exemptions for physicians at or near retirement age, for small or rural physician practices that are facing challenges meeting meaningful use requirements, and for specialists who are unable to meet many of the measures due to their scope of practice.**

<u>Evaluation Process is Lacking and Essential to Improving the Program</u>

We realize and appreciate the amount of time that the members of the Health IT Policy Committee and workgroups have spent to thoughtfully consider, develop, and recommend measures for Stages 2 and 3. Nonetheless, **we believe that it is a serious mistake to keep adding stages and requirements to the meaningful use program without evaluating Stage 1 of the program.** In addition, an evaluation should occur between each stage of the meaningful use program and prior to finalizing the requirements for the next stage. It makes no sense to add stages and requirements to a program when even savvy EHR users and

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[2] http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/Oct_Medicare_Incentive_Payments.pdf

specialists are having difficulty meeting the Stage 1 measures. It is incumbent upon the Department of Health and Human Services (HHS) to pursue an external, independent evaluation to improve, and inform the future of this program. An external, independent evaluation of Stage 1 of the program prior to the development of Stage 3 requirements will help to identify: measures that make sense and can be reasonably achieved; functionalities that vendors can build into EHRs and the timeframe required to build, test, and fully implement these functionalities; and meaningful use requirements that are reasonable for CMS and ONC to propose and pursue. Even large information systems like Intermountain Healthcare that have a long history of using EHRs have indicated in 2012 testimony before the U.S. House Subcommittee on Science, Space, and Technology that meeting all of the Stage 1 meaningful use requirements was difficult for them to achieve, and expressed concern about the unintended consequences of moving full speed ahead to develop and finalize Stage 3 requirements without a thorough assessment of Stage 1 and our current Health IT infrastructure and capabilities.[3] **We are hearing more and more from physicians that the meaningful use program has become a large data collection process which deflects attention and time from relevant data needed to care for patients.** For example, we continue to hear from many physicians that the requirement to provide clinical summaries to patients is unhelpful either because of the way the EHR presents the information to the patient or because some of their patients have indicated that they do not need a lengthy summary. Given the concerns raised with the current program, an external, independent evaluation is necessary to improve and inform the future of the program. The evaluation results should also be shared with the public and the public should have an opportunity to provide feedback.

Recommendations:

1) **HHS should use regulatory authority to hold off developing Stage 3 of the program until an external, independent evaluation of Stage 1 of the program is completed, and the results and recommendations for resolving issues that are identified are shared with the public for their feedback.**

2) **HHS should implement an evaluation process between each stage of the meaningful use program and prior to finalizing the requirements for the next stage.**

3) **EHR vendors should also be surveyed on their ability to incorporate into their software, within the timeframes proposed, capabilities proposed by the Health IT Policy Committee prior to the issuance of regulations requiring new functionalities and measures.**

[3] http://science.house.gov/hearing/subcommittee-technology-and-innovation-meaningful-use-delivering-meaningful-results

Usability of Certified EHRs Should be Addressed

The International Organization for Standardization (ISO) has defined usability to mean "[t]he extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use." There is a direct correlation between EHR adoption and the usability of an EHR. Physicians cite EHR usability as a key factor in their decision to purchase an EHR system. According to the Healthcare Information and Management Systems Society (HIMSS) EHR Usability Task Force, "…usability is one of the major factors – *possibly the most important factor* – hindering widespread adoption of EMRs."

EHRs should facilitate care coordination, practice efficiencies, and enhance processes that improve health outcomes. The usability of EHR products should also support decision-making, not circumvent the need for critical thinking. Both the Agency for Healthcare Research and Quality (AHRQ) and the National Institute of Standards and Technology (NIST) have studied the issue of EHR usability and adoption rates. The May 2010 AHRQ report, *Electronic Health Record Usability Vendor Practices and Perspectives*, indicated that "[d]riving the EHR market toward creation of usable products requires development of a process that accurately identifies usable products, establishes and disseminates standards, and encourages innovation."[4]

The meaningful use program offers physicians an unprecedented opportunity to invest in and use EHRs as well as other systems, including computerized physician order entry (CPOE). To date, ONC has certified over 2,000 EHR products. While ONC's website lists these certified products, it does not provide any information on their usability. We are pleased to see that ONC has adopted two new certification criteria related to patient safety—one that focuses on the application of user-centered design to medication-related certification criteria, and another that focuses on the quality management system (QMS) used during the EHR technology design. However, more research is needed to evaluate the efficacy, effectiveness, and safety of EHR and CPOE systems and ensure vendor accountability for these systems. In addition, although ONC's Regional Extension Centers (RECs) have been tasked with helping primary care physicians select an appropriate EHR product for their practices, we believe information regarding an EHR's usability needs to be made available, so that physicians in any specialty can use this information to determine which EHR product(s) best meet their practice workflow and specialty needs.

The AMA is also very concerned with the viability of the more than 2,000 certified EHR products and the likelihood that not all of these products will be around for the long-term, which is a reality that the industry is already experiencing. Some vendors may also decide

[4] http://healthit.ahrq.gov

not to re-certify for future stages of the program, which would expose many physicians to extreme financial hardships. ONC should consider requiring vendors of certified EHR products to commit to support subsequent stages of the meaningful use program. In addition, according to recent reports, nearly 50 percent of physician practices will change EHR vendors at some point for a variety of reasons. Physicians should also be protected from excessive vendor charges if a physician changes his/her EHR vendor and needs assistance transferring data from one system to another.

Usability standards being included in the certification criteria will be critical for ensuring that physicians invest their resources in EHR, CPOE, as well as other health IT products that work for them. Physicians are not only concerned about the viability of the EHR product(s) that they have significantly invested in, but are also concerned about potential liabilities from EHR system design and software flaws as well as lack of interoperability among EHR systems that could result in incomplete or missing information, which may lead to errors in patient diagnosis and treatment (e.g., patient matching). The Health IT Policy Committee is considering a meaningful use measure requiring health care providers to conduct a health IT safety risk assessment. We seek clarification on this proposal. Without clear standards and guidance, this measure could be burdensome for health care providers, especially smaller practices, to meet.

The AMA is also concerned with the approach adopted by ONC that no longer requires certified EHR modules to meet privacy and security requirements. Physicians are not IT experts and should only be responsible for the behavioral aspects of meeting privacy and security requirements—what they are able to control. It is unreasonable to place the burden on physicians to determine whether each and every EHR module that they use meets the privacy and security requirements under the meaningful use program. Moreover, we believe that this policy adopted by ONC favors complete EHR products over modules and could deter physicians from purchasing EHR modules. We recommend that more attention be paid during the certification process to address physician usability concerns.

Recommendations:

1) **CMS and ONC should collect data based on an EHR user (physician) satisfaction survey and disseminate survey results on usability experiences based on practice size, specialty type, and geographic location, and incorporate this feedback into future certification processes.**

2) **CMS and ONC should add additional usability and patient safety criteria for the EHR certification process.**

3) **CMS and ONC should promote innovation in EHR design and the meaningful use program requirements that not only address usability, mitigate user liability,**

and patient safety concerns, but can be more seamlessly integrated into smaller and/or rural practices that do not have the luxury of resources to completely redesign the way they work to accommodate their EHR.

4) **ONC should coordinate efforts with the AMA as well as other patient safety stakeholders to increase our understanding of risks associated with health IT and develop solutions to improve the safe design, implementation, and use of health IT.**

5) **ONC should require certified EHR modules to meet privacy and security requirements.**

6) **ONC should require certified EHR products to be capable of producing reports to confirm that physicians have met all (not just some) of the meaningful use measures. These reports should satisfy internal and external audit requirements.**

Health IT Infrastructure Barriers Should be Resolved

The fundamental building blocks needed to achieve widespread exchange of health care information are still under construction (e.g., identity authorization, consent management, privacy/security issues, data validation, etc.). Interoperability among systems that health care providers use is widely acknowledged as the key to achieving the value proposition for EHR use—both in terms of helping facilitate patient information exchange to drive quality improvement and delivering greater financial efficiencies to our health care system. While the AMA recognizes the important work underway in the industry to address the interoperability concerns, more immediate action is necessary. If physicians and other health care providers are unable to securely, accurately, and effectively exchange health data about their patients, the promise that health IT holds for enabling high quality and efficient care will just be a pipe dream. ONC and CMS have the responsibility to ensure that health care providers are able to use well-tested standards and securely exchange health information in the health care delivery system.

Each stage prescribed in regulation calls for more and more requirements, which becomes increasingly difficult for physicians to meet due to Health IT infrastructure and interoperability barriers. As a result, physicians have to purchase expensive customized EHR interfaces to connect with other health care providers, with health information exchanges (HIEs), and to meet Stage 2 measures. **A survey by the Bipartisan Policy Center revealed that more than 70 percent of clinicians surveyed identify lack of interoperability, lack of an information exchange infrastructure, and cost of setting up and maintaining**

interfaces and exchanges as major barriers to health IT use.[5] National standards and a national Health IT infrastructure need to be established to enable the secure, accurate electronic sharing and exchanging of health information amongst health care providers. We urge ONC, CMS, and other relevant federal agencies, including NIST, to better coordinate efforts to develop and fully test uniform standards on interoperability and secure HIEs through an open, transparent consensus process with the private sector. Adding more and more measures to the meaningful use program that rely on a bilateral interoperable infrastructure that does not exist is a step in the wrong direction. **Improving the Health IT infrastructure to allow physicians to readily and securely exchange patient data with other health care providers should be made a top priority and take precedence over developing future stages of the meaningful use program.**

Recommendations:

1) **ONC, CMS, and other relevant federal agencies including NIST should work to develop and fully test uniform standards on interoperability and secure HIEs through an open, transparent consensus process with the private sector.**

2) **Stage 3 should be delayed until a nationwide interoperable network is fully developed and meaningfully operating or at the very minimum; Stage 3 should not contain any measures that rely on information exchange if the Health IT infrastructure is lacking for physicians.**

3) **Before any new meaningful use objectives/measures that involve sharing and exchanging of patient data are finalized, the costs for physician practices including interface expenses should be analyzed and considered.**

4) **Physicians should not be required to meet meaningful use measures that require data sharing if they reside in an area where the infrastructure does not exist or the cost to implement would be prohibitive.**

[5] http://bipartisanpolicy.org/sites/default/files/Clinician%20Survery_format%20(2).pdf

Additional Recommendations for Improving the Meaningful Use Program

In addition to our recommendations above, we urge the Health IT Policy Committee, ONC, and CMS to seriously consider further comments and recommendations:

Streamline regulatory requirements

We are concerned that decisions are being made on the meaningful use program, such as increasing the volume of core measures, without considering the impact on physician practices as they struggle to meet a number of regulatory requirements in addition to meaningful use, all in the same years. Physicians are struggling to meet numerous deadlines under separate regulatory programs including PQRS, value based modifier, and ICD-10 implementation, all of which require significant financial investment, impact office workflow, and place physicians at risk of facing multiple financial penalties in the same years. More needs to be done to align these programs to avoid regulatory overload. **We strongly recommend that the Health IT Policy Committee, ONC, and CMS do a better job of factoring in the overall burden to physicians when additional measures are added to the core/menu sets of the meaningful use program and thresholds for multiple measures are significantly increased all at once.**

Align the meaningful use program requirements with other regulatory programs

It is imperative that the Health IT Policy Committee and HHS work with physicians and other stakeholders to develop a roadmap outlining the various, competing health IT, quality, and the Health Insurance Portability and Accountability Act (HIPAA) privacy, security, and administrative simplification requirements to ensure that the timelines are synchronized to the greatest degree possible to minimize the burdens on physicians. Expanding the meaningful use program during a time that physicians have to comply with other Medicare regulatory programs including PQRS and ICD-10 is unreasonable. The stage approach is purely a regulatory invention and not required by statute. **Congress did not require formal stages for the meaningful use program, so we urge CMS and ONC to pursue a regulatory fix that would halt the staged approach until the health IT and regulatory barriers raised are fully resolved.**

Build in three years between the stages

We believe that there should be a minimum of three years between the stages of meaningful use—one year for rulemaking, one year for product development, and one year for implementation. This will allow adequate time for vendors to test and build in functionalities into EHR products and for an evaluation process so that improvements can be made to the program and EHR technology and infrastructures are fully operational prior to the launching of a new stage.

Make measures outside the physician's control optional to meet

Measures that require adherence from a party other than the physician, at the very minimum, should be placed in the menu set (e.g., SGRP 204A, SGRP 207). Physicians cannot force patients to view their health information on-line or send secure messages electronically. Without an incentive to them directly, many Medicare patients are unlikely to participate in this measure regardless of their ability to access the Internet. For physicians with populations of the elderly, rural and/or low income areas, this measure would be especially difficult to meet. While patients should be informed of the benefits and uses of viewing their health information on-line or sending secure messages to their health care providers, physicians should not bear the risk of being penalized for something that is an independent and potentially appropriate decision made by the patient.

Place new measures in the menu set

Many of the proposed new measures for Stage 3 require implementation of new standards, many of which do not currently exist. Given the amount of time it takes to develop standards, this seems to be an unreasonable hurdle unless ONC and CMS have the resources necessary to invest in the rapid development of such standards and to put them through the existing consensus-based organizations and processes. New measures by definition are untested and therefore all new measures (e.g., SGRP 112, SGRP 130, SGRP 204B, SGRP 204D, SGRP 206, SGRP 305, SGRP 401B, IEWG 101) should be placed initially in the menu set for Stage 3.

The AMA recommends that resolving current technological barriers that adversely affect physicians' use of EHRs be considered an immediate, top priority. Given the above-mentioned concerns on the health IT infrastructure and lack of interoperability, we believe that efforts would be better spent focusing first on enabling physicians to exchange patient information with other health care providers. Furthermore, we remain deeply concerned that CMS and ONC are holding physicians accountable for their patients' actions even when patients do not have the ability or choose not to use patient portals.

Do not move Stage 2 menu set measures to the Stage 3 core set, or substantially revise Stage 2 core measures until barriers are thoroughly assessed and overcome

Prior to moving a measure from the Stage 2 menu set to the core set for Stage 3, or substantially revising a Stage 2 core measure, the expected impact, the expected value, risks (both clinical and administrative), evidence of efficacy, administrative burden, costs to physicians, and technological standards of the move should be thoroughly assessed. For example, the Stage 2 menu measure on imaging results (e.g., SGRP 118) should not be substantially revised and/or moved to the Stage 3 core set until it is thoroughly assessed. In a case where a family physician orders a CT scan and sends the patient to an imaging center to

have it done, is it reasonable to require the family physician to have the image accessible in his/her EHR? In addition, it is important to consider that CTs, MRIs, and other such tests are very large and high-resolution files. These images are typically maintained in a separate radiology information system and accessed using special monitors and servers. It is also important to take into account that the EHRs the vast majority of physicians use should be able to consume and display the final radiology report since this report is what most physicians base their decisions on. Another example of a proposed measure that requires further assessment involves SGRP 206 which states that eligible professionals (EPs) have to provide at least 80 percent of patient specific education resources in at least one of the top five non-English languages spoken nationally, based on the EP's local population. Physicians will consider this another unfunded mandate that will increase costs for their practice. Other proposed measures also need to be assessed prior to any substantial revisions (e.g., SGRP 404, SGRP 405).

Assess measures that require EHR vendors to build in functionality and pilot test them prior to proposing them as a meaningful use measure

Measures that require EHRs to provide certain functionality should be pilot tested and evaluated prior to being proposed as Stage 3 requirements (e.g., SGRP 105, SGRP 106, SGRP 107, SGRP 122, SGRP 204B, SGRP 204D, SGRP 209, SGRP 401A, IEWG 102).

Base requirements such as percentage thresholds on evidence and experience

Percentage thresholds should not be increased for certain measures (e.g., SGRP 101, SGRP 113, SGRP 114, SGRP 115, SGRP 207, SGRP 303) until there is a thorough evaluation of these measures based on evidence and the experience of physicians and other end users.

Align federal and state privacy and security requirements

One of the major concerns with and barriers to EHR and mobile technology use and participation in HIEs are the conflicting federal and state privacy and security laws. We are also concerned about potential liability that physicians could face if their vendor's EHR or the HIE that they participate with are hacked or if a cloud-based product that they use is illegally accessed. Legal barriers to HIE implementation also exist due to lack of laws in some states, conflicting state and federal laws, and lack of national guidelines especially when various laws conflict. While HIPAA sets the floor it can be superseded by more stringent state privacy laws which makes compliance with state and federal requirements extremely challenging for physicians participating in regional HIEs who must comply with multiple privacy and security laws that may conflict. In addition, the forthcoming HIPAA privacy rule expected to be released by the Office for Civil Rights (OCR) in 2013 could have a significant effect on physicians' willingness and ability to adopt and use EHRs. As more and more physicians transition their paper records to electronic ones and participate in HIEs

with other health care providers at local, regional, and even national levels, the issue of patient informed consent is also being raised and debated. We recommend that guidance be provided to physician practices that are considering implementing an informed consent process, including helpful forms and formats. We urge HHS to work with states to develop uniform privacy and security recommendations that: (1) adequately protect patient and health care provider data from inappropriate access, use, or disclosure; (2) do not unduly burden physicians and other health care providers from the ability to operate their practices or care for their patients; and (3) eliminate barriers to the use of mobile technology and participation in HIEs and the interstate exchange of health information. In addition, we urge OCR to factor in the impact that overly burdensome privacy and security regulations could have on EHR adoption and physician participation in the meaningful use program.

Make improvements to the meaningful use program prior to the pursuit of audits

The November 2012 Office of the Inspector General's (OIG) early assessment of CMS' oversight of the Medicare EHR incentive program included several recommendations that the AMA fully supports and that should be implemented prior to the pursuit of audits. We agree that CMS should issue better guidance on the type of documentation it expects health care professionals and hospitals to maintain to support their compliance with meeting the meaningful use program requirements. In addition, the AMA agrees with the OIG that ONC should require certified EHR technology to be capable of producing reports to confirm that physicians and other EPs have met all (not just some) of the meaningful use measures. ONC should also improve the certification process for EHR technology to ensure that reports generated from an EHR are accurate. These improvements must occur prior to the pursuit of audits. Moreover, the AMA does not support prepayment audits in the meaningful use program as they would impose additional burdens on physicians who are already having a difficult time keeping up with the separate program requirements for multiple Medicare health IT and quality programs.

Recommendations on Clinical Quality Measures (CQMs)

Patient Centeredness: Patient-reported and Patient-Directed Data (QMWG07, 08)

Work is underway to incorporate patient-generated self-assessment tools, health surveys, etc., into CQMs. Although patient-generated data will likely have significant value and application, this information will first need to be collected and stored separately to ensure the data is valid. Also, the usability of this information will vary based on data type, as collecting patient generated data with respect to functional status is very different from patients reviewing the information in their EHR and requesting a modification.

A good approach may be to initiate a multi-step pilot program: (1) create a mechanism to collect patient-generated data in the EHR; (2) begin data collection related to a specific

condition/diagnosis/eCQM; (3) analyze and validate data; and 4) determine how to apply/include data to eCQM. For the pilot, diabetes, cardiac health, obesity measures may have good opportunities for patients and physicians to be involved more cooperatively in their health care. For example, a patient can maintain an electronic log for physical activity or diet, check blood pressure/blood sugar daily, and insert personal goals, such as "decrease BMI from 35 to 33." This information could be populated into a separate field in the EHR by the patient, which the physician can access. Then, this information can be used in follow up encounters between physician and patient and facilitate shared decision making on the patient's care plan.

CQM Pipeline: Measure Development Lifecycle (QMWG11, 12)

A shift away from retooling legacy paper-based CQMs in exchange for designing eCQMs de novo may be a reasonable and desirable course of action for many measures. This is particularly true for measures that need so much "renovation" to effectively re-tool into eCQMs that it may be more resource and time intensive than to start from scratch. However, the retooling of existing measures allows for broader participation of various specialties, which can greatly enhance participation in the EHR meaningful use program. **Measure developers and stewards must be given flexibility to determine whether a new or retooled CQM is appropriate.**

CQM Pipeline: MU Alignment with Functional Objectives (QMWG14, 15)

The AMA-convened Physician Consortium for Performance Improvement (PCPI)™ recognizes great value in the alignment of CQMs and MU Objectives. Such alignment will ensure that the data for CQMs are captured through the course of the clinical workflow. The meaningful use objective to "use clinical decision support to improve performance on high-priority health conditions," is in general an important objective. Measure developers are uniquely positioned to make recommendations on data capture for CQMs because they understand the measure. Moreover, measure developer involvement in these recommendations will further inform the development of measures for electronic data sources in the future.

CQM Pipeline: Domains and Exemplars (QMWG16)

The following domains should be high priorities for meaningful use Stage 3: (1) engaging patients and families in managing their health and making decisions about their care. A measure concept related to patient feedback and accountability could be developed for this domain, especially for the following chronic diseases: diabetes, cardiac health, and obesity; and (2) ensuring that patients receive well-coordinated care within and across all health care organizations, settings, and levels of care. A measure concept on functional status/comfort/pain management can be developed, which includes multiple care settings and

treatment such as pharmacotherapy, physical therapy, acupuncture, fitness, and mental health.

CQM Pipeline: Domains and Exemplars (QMWG17)

In the development of measures, measure developers struggle with drafting measures which may need more frequent and immediate updating to incorporate the latest evidence or clinical guidelines. Due to the length of time that is required to meet HHS timelines for inclusion in national programs, combined with the measure life cycle, including development, testing and eSpecification and related steps of NQF endorsement, there is a significant time lag from the time a measure is developed to the time when it is implemented. **We urge HHS to consider increased flexibility in program design and establish a means to incorporate the newly developed measures that will leverage EHR technology and factor in new clinical evidence, focusing on the goal of improving health outcomes for patients.**

CQM Pipeline: MU and Innovation (QMWG19, 20, 21, 22)

Following the surge in health care providers' meaningful use of EHRs and implementation of CQMs, an increased interest in developing eCQMs among providers will likely also rise over the next few years. While there are potentially many advantages to allowing an alternative measure pipeline to develop, it is unlikely that practice sites or even sophisticated integrated delivery networks possess the necessary expertise with the eCQM standards currently in use (e.g., Quality Data Model, HL7 HQMF eMeasure). Additionally, developing eCQMs at the individual practice level will make performance comparisons across practice sites difficult. Standardized measures (using standardized specifications) can be used to compare results nationally, which is especially important when there are financial penalties to consider. **The proposal to allow provider-initiated eCQMs should first be piloted before it is used as a component of the EHR meaningful use program, even on a voluntary or optional basis.** Such efforts would require additional resources for both the public and private sectors. Additionally, measure harmonization is an important consideration. As the field of measure developers expands, there is an increased risk of unharmonized measures and duplicative efforts. Providing incentives to coordinate efforts and co-produce eCQMs are prudent considerations as well.

Quality Improvement Support: Architecture and Standards (QMWG27)

The AMA-convened PCPI™ recommends standardized specification to ensure consistent application and use. Efforts by PCPI to create a National Quality Registry Network (NQRN) could support multisource data exchange through the integration of multi-specialty registries. Utilizing health care registries can help achieve the goals ONC has outlined for eCQMs and EHRs. By collecting data across multiple clinical care settings, gaps in care and quality indicators can be identified and monitored at the national level. Registries can

facilitate outcomes measurement and aid in the development of new measures in a more efficient and standardized manner.

Specific Recommendations on the Proposed Stage 3 Measures

Keep e-prescribing percentage threshold at 50 percent and recommend a uniform standard for prior authorization (SGRP 103)

We agree that the e-prescribing measure threshold should be maintained at 50 percent. Over 135,000 EPs received e-prescribing penalties in 2012 under the Medicare e-prescribing penalty program. In addition, we have heard concerns from physicians who are unable to meet the percentage threshold requirements due to issuing a large volume of mail-order prescriptions. Many mail-order pharmacies do not accept electronic prescriptions and still require that prescriptions be faxed in. Challenges still remain on the e-prescribing of controlled substances including more restrictive state laws and the lack of widespread availability of health IT products both for physicians and pharmacies that include the functionalities required by the Drug Enforcement Agency (DEA). Until the many challenges associated with e-prescribing referenced above are resolved; the percentage threshold for the e-prescribing measure should stay at 50 percent, and EPs should have the discretion (not be required) to review the drug formulary, if it is readily available in Stage 3. Physicians should always retain the authority to prescribe a drug that is not on the formulary or a drug that is not generic. A broad exclusion category for physicians who cannot meet the e-prescribing threshold requirement due to their individual hardship should also be established.

We also recommend that the Health IT Policy Committee urge CMS to work toward finalizing the remaining e-prescribing standards for prior authorization, structured and codified SIG, and clinical terminology. The Medicare Modernization Act of 2003 (MMA) specifically mandates the development and promulgation of uniform standards, including prior authorization. The need for real-time prior authorization for Medicare patients is critically important given that most Part D plans require prior authorization for selected drugs. The fact that there has not been a standard adopted for prior authorization continues to pose significant workflow and inefficiencies for physicians. Physicians should be able to obtain real-time information about their patients' benefits and medications authorization status. Moreover, there is significant time and cost savings that could be realized by implementing a prior authorization standard. While CMS' proposal simply updates the standards used in the Medicare Part D program to communicate information between health plans/pharmacy benefit managers and prescribers including what drugs are on a formulary and the prior authorization requirements, it does not address the actual process physicians need to obtain for prior authorization. The AMA believes that the best automated solution for electronic prior authorization allows for an automated, end-to-end physician workflow for all authorizations that is integrated within the practice management/electronic health record (PMS/EHR). This solution will also simplify the process for physicians using stand-alone

e-prescribing systems/modules.

Retire certain measures from the meaningful use core set (SGRP 108, 109)

We agree that certain measures including measures for recording vitals signs and smoking status (SGRP 108, SGRP 109) should be retired from the core set and continue to be included in the clinical quality measure set for physicians to select from so that progress can be tracked for these measures via CQM reporting. Also, we seek clarification on whether the Health IT Policy Committee's proposal to retire SGRP 108 and 109 applies to Stage 3 only or also to all stages including previous ones.
We believe that demographics information collection (SGRP 104) should continue to be included as a core measure given that collection of this information is critical to patient management. We also support the development of EHR certification criteria that would allow physicians to record their patient's gender identity and/or sexual orientation, disability status, occupational demographics, etc., at the physician's discretion given that the capturing of this data is important for quality of care purposes for the appropriate specialties.

In addition to ensuring that demographic data continue to be collected, collecting *valid, reliable, and useable* data on the demographic characteristics of patients receiving care is critically important. To those ends, we recommend that: (1) EHR vendors be encouraged to adhere to demographic data collection standards articulated by the Institute of Medicine (www.iom.edu/Reports/2009/RaceEthnicityData.aspx.) and HHS (http://aspe.hhs.gov/datacncl/standards/ACA/4302/); (2) EHR vendors be encouraged to develop and implement electronic user support tools within EHRs (such as prompts to support collection of data from the patient rather than based on observation, and evidence-based scripts for asking patients to self-report on demographics) to ensure that patient-reported data are collected in ways that are most likely to yield valid and reliable responses; and (3) EHR vendors be encouraged to develop user-friendly mechanisms to quickly display quality data stratified by race, ethnicity, primary language, and other demographic factors.

Reduce the number of clinical decision support interventions required for Stage 3 and establish an exclusion category for the measure to enable the functionality for drug-drug and drug-allergy interaction checks (SGRP 113)

We are concerned with the high threshold proposed for implementing clinical decision support (CDS) interventions (SGRP 113). Some physicians report that there are still no CDS interventions that are appropriate for their scope of practice. The financial and staff resources associated with customizing these forms and tools should also be taken into consideration before requiring a threshold of 15 CDS rules be implemented in Stage 3. The proposal to implement 15 CDS interventions related to five or more clinical quality measures would be challenging for certain specialists and sub-specialists who may not need to

implement so many CDS interventions for their particular patient populations given the specific type of care that they provide.

While we support the proposal that calls for the EP to enable and implement the functionality for drug-drug and drug-allergy interaction checks (SGRP 113) for the entire EHR reporting period, we recommend that physicians be provided with the flexibility to use their judgment regarding where to establish the threshold setting. In addition, we recommend that an exclusion category be established for specialists who neither routinely prescribe nor actively participate in patient pharmacy management.

Allow physicians the option of meeting Stage 1 or Stage 2 percentage thresholds in lieu of the Stage 3 percentage thresholds in the event that meeting the Stage 3 measures would be burdensome (SGRP 101, 113, 114, 115, 302, 303, 401A)

We recommend that physicians have the option to meet certain measures (e.g., CPOE [SGRP 101], CDS [SGRP 113], incorporating lab results [SGRP 114], generating lists of patients for multiple conditions [SGRP 115], medications reconciliations when the EP receives a patient from another setting [SGRP 302], transitions of care [SGRP 303], receiving immunization history [SGRP 401A]) using percentage thresholds established under Stage 1 or Stage 2, if the Stage 3 percentage thresholds would be burdensome to meet due to technological or financial challenges.

Establish an exclusion category for specialists regarding prevention reminders (SGRP 116)

We support the Health IT Policy Committee's recommendation to establish an exclusion category for specialists for SGRP 116. Requiring that physicians send patient reminders for preventive or follow up care would be challenging for certain specialties and sub-specialists given that some of the services they provide involve only one visit or limited visits so there would be no need to send a reminder to the patient for a followup visit. For example, emergency medicine is exclusively unscheduled, episodic care. Another example to consider are services provided by a gastroenterologist who may provide consultation and procedure for a patient but then return all further care to a primary care provider. We recommend that the exclusion category be broad enough to cover physicians for whom routine patient reminders would not be contextually relevant or appropriate.

Avoid imposing arbitrary, rigid, conflicting deadlines for meeting certain measures (SGRP 120, SGRP 122, SGRP 204A, SGRP 205)

We are concerned with multiple measures that impose arbitrary, rigid deadlines for meeting Stage 3 measures. In addition, physicians will have a difficult time keeping up with all of the varying deadlines under Stage 3. One measure (SGRP 120) requires physicians to meet a four calendar day turn around time for each patient office visit in a calendar year, while

another measure requires physicians to meet both a 24 hour and a four business day turn around time for different components of each patient visit (SGRP 204A). Furthermore, we are concerned that these tight deadlines may not be workable in all practice environments. For example, in some cases where a physician has determined that there is a chance a patient could harm themselves if they viewed their medical information, the physician should have the discretion to make the information available when appropriate and not be forced to comply with an arbitrary deadline. This discretion is consistent with laws in many states. Also, patients who travel to tertiary care centers may return to their homes for radiographic or lab testing. These results may be forwarded to the originating institution, but the process may take several days, which makes it difficult for physicians to meet the arbitrary, rigid deadlines. We strongly recommend that these arbitrary, rigid, and conflicting deadlines be removed from the meaningful use program. Moreover, imposing such deadlines could be viewed as the federal government attempting to dictate the practice of medicine.

Place all new measures in the Stage 3 menu set (*SGRP 112, SGRP 122, SGRP 130, SGRP 204B, SGRP 204D, SGRP 206, SGRP 305, SGRP 401B, and IEWG 101)*

New measures by definition are untested and therefore all new measures should be placed initially in the menu set for Stage 3. For example, we agree with the Health IT Policy Committee that the new measure SGRP 204B should be placed in the menu set. There is also concern with the SGRP 204B measure that without the face to face communication between a physician and the patient, the average patient may disengage from this type of activity.

Do not develop overly prescriptive measures (SGRP 205, SGRP 303)

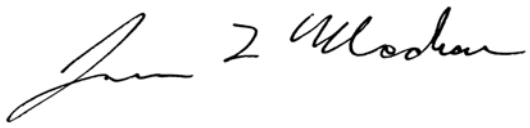
We recommend that measures such as producing clinical summaries for each patient (SGRP 205) not be overly prescriptive by requiring physicians to produce the same information for every patient. Physicians are in the best position to determine what information needs to be included in the clinical summary for a particular visit. In some cases, a short note stating what was discussed and what was agreed upon would be more useful than providing a patient with an exhaustive laundry list or multiple page data dump after each visit. There are some specialists (e.g., oncologists) who may see patients multiple times in a given week and providing the same clinical summary for multiple visits in a given week would not be helpful to the patient. We do not want the meaningful use program to be viewed as a program that is dictating the practice of medicine or promoting “check the box” activities that do not support practice efficiencies or help improve quality of care delivery. Therefore, we strongly recommend that flexibility be provided on clinical summary content and the production requirement.

Recommendation on the proposed measures beyond Stage 3

Although the Health IT Policy Committee proposed measures for stages beyond Stage 3, we believe that it is premature to comment on these proposed measures. We reiterate our recommendation that the best approach is for HHS to use regulatory authority to hold off on developing Stage 3 as well as future stages of the program until an external, independent evaluation of Stage 1 of the program is completed and a nationwide interoperable network is fully developed and meaningfully operating.

We are committed to working with the Health IT Policy Committee, CMS, and ONC to ensure that the meaningful use program truly fosters EHR adoption, use, and successful physician participation in the Medicare and Medicaid EHR meaningful use programs. Should you have questions or require additional clarification about these comments, they may be directed to Mari Savickis, Assistant Director, Division of Federal Affairs, at 202-789-7414 or mari.savickis@ama-assn.org.

Sincerely,



James L. Madara, MD