

May 7, 2012

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare and 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—Stage 2; CMS-0044-P; RIN 0938-AQ8**

Dear Acting Administrator Tavenner:

The undersigned organizations are pleased to provide comments on the proposed rule for implementing Stage 2 of the Medicare and Medicaid electronic health record (EHR) incentive programs. We share the Administration's goal of wide-spread EHR adoption. We remain, however, concerned that the Administration's meaningful use criteria will actually discourage physician participation in the meaningful use EHR program rather than encourage it. Physicians are in various stages of incorporating well-developed EHRs into their practices to improve quality of care delivery, enhance patient safety, as well as support practice efficiencies, but barriers remain. An April 2012 *Health Affairs* article indicated that while about half of all eligible office-based physicians intended to apply for either the Medicare or Medicaid meaningful use incentives, only 11 percent of physicians surveyed intended to apply for incentives and had EHRs capable of meeting two-thirds of the Stage 1 core meaningful use measures.¹ This recently published survey highlights that physicians are facing technological and other challenges in meeting all of the required meaningful use program measures. Our comment letter recommends needed changes to the Stage 2 proposal and solutions for synchronizing the multiple health IT and quality programs currently underway in order to increase physician participation rates. **Changes to the meaningful use program including the proposed Stage 2 criteria and penalty programs are necessary to ensure that the meaningful use program lives up to its intended purpose—to help physicians adopt, implement, and meaningfully use EHRs.**

Our principal recommendations for Stage 2 measures are as follows:

1. **Evaluate Stage 1 to inform Stage 2:** CMS should survey physicians who elected to participate and those who elected not to participate during Stage 1 of the incentive program and identify barriers to and solutions for physician participation prior to finalizing Stage 2 requirements. In addition, prior to moving a measure from the Stage 1 menu set to the core set for Stage 2, or prior to adding new core measures for Stage 2, 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;
2. **Measures for meeting meaningful use should include exclusions and factor in relevancy:** For example, reasonable exclusions for many requirements should be included so that a physician can opt out of the measure if the measure has little relevance to the physician's routine scope of practice;

¹ <http://content.healthaffairs.org/content/early/2012/04/19/hlthaff.2011.1315.full.pdf+html>

3. **Avoid high thresholds:** High thresholds should be avoided for new measures and for measures that cannot be met due to the lack of available, affordable, well-tested tools or abundant bidirectional health information exchanges;
4. **Only use measures within a physician's control:** Measures that require adherence from a party other than the physician should be eliminated (e.g., measures based on patient's use of technology).
5. **Additional improvements needed on final Stage 2 measures:** Any proposed new measure for Stage 2 should initially be in the menu set of options, and if an increase in the threshold percentage of a Stage 1 measure is warranted in Stage 2, then the increase for Stage 2 should be no more than 10 percent;
6. **Good faith effort to meet measures in Stage 2 should count:** Physicians should not have to meet all 20 measures plus clinical quality measure reporting to prove that they are a meaningful user of a certified EHR. Allowing physicians to opt-out of a certain number of measures (e.g., three or more) is the type of flexibility needed in the meaningful use program that would encourage more physician participation and increase participation rates;
7. **Medicare/Medicaid meaningful use program rules should only apply to Medicare/Medicaid patient populations:** CMS should make it clear that physicians are not required to apply the Medicare/Medicaid meaningful use program requirements to their non-Medicare/Medicaid patient populations in order to be eligible for Medicare or Medicaid EHR incentives or in order to avoid Medicare financial penalties;
8. **Meaningful use as well as other health IT and quality penalty programs should not be back-dated and a number of exemption categories detailed in this letter should be established:** We oppose CMS' proposal to back-date the meaningful use reporting requirements under the penalty program so that a physician would face the 2015 penalty based on 2013 or 2014 data. A number of exemption categories should be established and the exemptions should apply for five calendar years to minimize filing burdens and to allow time for CMS to reassess program requirements and timelines. If the participation rates are low and/or too many physicians are applying for exemptions, then significant changes need to be made to the meaningful use program requirements in the penalty phase, and exemption categories may need to be revised and additional ones developed;
9. **More needs to be done to synchronize the multiple health IT programs:** CMS should add more exemption categories to the Medicare e-prescribing and meaningful use programs as detailed in this letter so that physicians are not unfairly penalized for participating in one program over the others;
10. **Establishment of an appeals process under both the meaningful use and e-prescribing programs is necessary:** In addition, we urge CMS to provide physicians with 180 days to file an appeal under the meaningful use program after receiving actual notice of determination(s) that are subject to appeal at all levels of appeal; and
11. **Recommendations on Clinical Quality Measure (CQM) reporting are as follows:**

Consider a third CQM reporting option: We urge CMS to allow eligible professionals (EPs) to report six clinically relevant CQMs, covering at least two domains. If an EP does not have clinically relevant measures, the EP's system must demonstrate zeros in the denominator for six measures covering at least two domains.

Support CQM Option 2: We support CMS' proposed Option 2, under which Medicare EPs, who submit and satisfactorily report Physician Quality Reporting System (PQRS) CQMs under the PQRS EHR reporting option using Certified EHR Technology, would satisfy their CQM reporting requirement under the Medicare EHR meaningful use program.

EPs should not be penalized for vendor non-certification: CMS should ensure that EPs are not penalized if it is later determined that a vendor has not met the EHR Technology certification requirements, especially if the EP is making a good faith effort to report CQMs under the meaningful use program.

EPs should not be penalized for measure mid-cycle removal: If a measure is removed from the program mid-cycle, EPs should simply have one (or more) less reportable measure(s) for that cycle, and should not be required to report on an additional measure(s) in place of the removed measure(s).

Testing of electronic specifications: CMS should ensure that electronic specifications for all CQMs are tested prior to vendors imbedding them into their systems for use, with CMS funding to ensure an appropriate testing process.

Exemption for EPs: CMS should exempt EPs from the CQM requirements of the EHR incentive rule until measures have been tested and vendors have shown they have met the certification requirements for the specific EHR Technology being utilized by an EP.

Stage 2 attestation: We support CMS' proposal to allow EPs to report CQMs through attestation during Stage 1 of the meaningful use program. We also urge CMS to continue to allow EPs to report CQMs through attestation during Stage 2 as well.

Include reporting of CQM exceptions in certification criteria requirements: CQM exceptions provide actionable information for patient care and are important to quality measurement, and therefore CMS should include the reporting of CQM exceptions, in addition to overall performance rates of CQMs, in the Stage 2 CQM certification criteria requirements.

General Comments on the Meaningful Use Program

While we support CMS' recommendation to delay Stage 2 until 2014, physicians need to be assured that their EHRs will be able to support Stage 2 measures well in advance of 2014. Physician practices need adequate training and have to adjust workflows in order to meet Stage 2 measures prior to the 2014 date. We are also very concerned that our previous recommendations for developing Stage 2 measures were not adequately considered by CMS. Throughout 2011, we urged CMS to build flexibility into the meaningful use incentive program to accommodate all specialists and their varying practice patterns and patient populations. By doing so, we believe more physicians would be able to take advantage of the EHR meaningful use incentives, which would help us achieve the desired outcome for the Medicare/Medicaid EHR program—accelerating the widespread meaningful use of technology by physicians and other health care providers to improve our nation's health care delivery system. We also recommend that Stage 2 be extended for a minimum of three years so that CMS has adequate time to evaluate Stage 2 prior to moving to Stage 3.

Comprehensive Survey on the Meaningful Use Program

To date, CMS and the Office of the National Coordinator for Health Information Technology (ONC) have not comprehensively surveyed physicians on Stage 1 measures to determine what works, what does not work, and what improvements need to be made for Stage 2 of the meaningful use program. The evaluation should also factor in practice size, geographic locations of practices, and specialty type. The low participation rates for 2011, which was the first year of Stage 1 of the EHR meaningful use program, suggest that Stage 1 measures need to be refined in

Stage 2. The Department of Health and Human Services' (HHS) own data indicates that in 2011, only 57 percent of physicians use EHRs², and in most cases they are not using a system that is comprehensive enough to meet the Stage 1 requirements. Given the extremely low physician participation rates in Stage 1, improvements should be made to the program to increase physician participation. We recommend that prior to finalizing the Stage 2 requirements, CMS fully evaluate the Stage 1 requirements and refine its Stage 2 requirements in accordance with the aforementioned recommendations. For example, **if CMS' evaluation of Stage 1 reveals that physicians did not participate in 2011 because they could not meet certain core measures, then adequate exclusions should be developed for these measures or these measures should be transferred to the Stage 2 menu set.** In addition, core measures should be limited to items for which it will clearly be possible for all EPs to meet the measure with technology that will be broadly available at the time the measure takes effect.

More Exclusion Categories

CMS' proposal to add a limited exclusion to many of the proposed Stage 2 measures that only exempts "any EP who has no office visits during the EHR reporting period" is insufficient. This limited exclusion does not take into account varying physician practice patterns. This narrow exclusion would deter many physicians from participating in the program given that not being able to meet just one measure disqualifies a physician from successfully participating in the program. In addition, CMS' proposal to move many of the measures from the menu set to the core set without a thorough assessment is troublesome. Overall, CMS' proposal for Stage 2 measures appears to be a "one size fits all" approach that requires all physicians, regardless of their specialty or patient population, to meet the same measures and thresholds. Please review our recommendations on additional exclusion categories for the proposed Stage 2 measures that are detailed in this letter. **Along with CMS' proposed limited exclusion categories, additional exclusion categories should also be developed in accordance with our recommendations for Stage 2 measures.**

Avoid High Thresholds

We are also concerned that many of the measures (e.g., incorporation of clinical lab test results, patient's electronic access to health information, data submission to registries) cannot be met without the availability of secure, bidirectional health information exchanges throughout the country. Without these health information exchanges, physicians would be excessively burdened with keying information into their EHRs in order to meet a significant number of measures with high thresholds in Stage 2. 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. Health IT interoperability and standards efforts have continued to evolve, and industry adoption is steadily increasing. However, in many cases expensive customized EHR interfaces are still needed to support EHR integration with health information exchanges. We are also concerned with high thresholds for measures (e.g., computerized provider order entry (CPOE)) that are still challenging for physicians to meet. **Therefore, high thresholds should be avoided for new measures, and measures that cannot be met due to the lack of available, affordable, well-tested tools or bidirectional health information exchanges, should not be required.**

Coordinated care requires knowing what others are doing, but, as is often the case, too many people involved in a patient's care do not have the means to or are not communicating with each

² <http://www.cdc.gov/nchs/data/databriefs/DB79.pdf>

other.³ Over the past decade, the health care community has associated fragmented care to: omissions or duplications in the care plan, delays in care and sicker patients, poor utilization of resources and higher costs, and patient confusion and harm. Although the health system is advancing care coordination concepts and building health information exchange structures, it can generally be said that health care has no care coordination system.⁴

CMS' decision to increase threshold amounts for Stage 2 measures from 30 to 60 percent (e.g., CPOE measure), from 50 to 80 percent (e.g., vital signs), or from 10 to 50 percent (e.g., patient access to health information in four business days) without a thorough assessment of Stage 1 is also of major concern. CMS' proposal to significantly increase threshold amounts is based on limited data. Since so few EPs have participated in the incentive program, CMS should not base its decision to increase threshold amounts on the low percentage of physicians who attested in 2011, but instead survey physicians who did not participate to determine which measures and thresholds caused physicians to decide not to participate in 2011, and why percentages were lower for some physicians who successfully attested. We recommend that threshold requirements be increased only after a thorough surveying of non-participating physicians takes place, and CMS should also factor in the overall burden to physicians when thresholds for multiple measures are significantly increased all at once. Since the overarching goal of the meaningful use program as outlined in legislation is to increase health care provider use of EHRs, then a more reasonable approach to increasing measure reporting thresholds should be considered. Therefore, **after a Stage 1 measure is assessed and deemed reasonable, the threshold amount should only be increased by 10 percent for Stage 2.** If physicians are able to successfully meet the 10 percent threshold increase in Stage 2, then a higher threshold should be considered for Stage 3.

Good Faith Effort to Meet Measures Should Count

Physicians should not have to meet all 20 measures plus clinical quality measure reporting to prove that they are a meaningful user of a certified EHR. If exclusion(s) (in both the core and menu sets) apply to a physician, then the exclusion should count towards meeting the program requirements. In addition, physicians should have an opportunity during the attestation process to explain any difficulties they had meeting meaningful use measures and should be able to opt-out of meeting three measures at minimum, and still be eligible to receive incentives or be able to avoid penalties. The focus of Stage 2 meaningful use should be on quality not quantity. **In summary, we urge CMS to limit the number of measures in the core set and expand the number of measures in the menu set, and develop appropriate exclusions for each measure. If an increase in the threshold percentage of a measure is warranted, then the increase for Stage 2 should be no more than 10 percent. In addition, allowing physicians to opt-out of a certain number of measures (e.g., three or more) is the type of flexibility needed in the meaningful use program that would encourage more physician participation and increase participation rates.**

CMS' Unauthorized Private Payer Data Use

We are extremely concerned that CMS has taken the position that physicians who are taking part in the Medicare or Medicaid meaningful use EHR incentive program are required to apply the meaningful use measures to their entire patient population, including their non-Medicare/Medicaid patient population. The American Recovery and Reinvestment Act of 2009 (ARRA: P.L. 111-5) clearly sets parameters that the meaningful use EHR incentive and penalty programs are only based on Medicare charges and payments (not private payer charges and

³ Thomas H. Lee & James J. Mongan. *Chaos and Organization in Health Care*; MIT Press, Cambridge, Massachusetts, 2009.

⁴ Id.

payments). Specifically, the law states that the incentives are equal to 75 percent of allowable Medicare Part B charges and subject to annual maximum limits. **CMS' expectation that a physician meet meaningful use measures for all of their patients, but only receive incentives based on their Medicare patients is highly unfair for physicians who have more private payer business than Medicare business, and this approach is not supported in statute.** Take, for example, meeting the clinical summary measure. In order to meet the proposed 50 percent threshold requirement for the Stage 2 clinical summary measure, a physician issuing clinical summaries for 500 Medicare patients and 2,500 private payer patients during the reporting period would have to issue clinical summaries for 1,500 patients (majority of whom are non-Medicare patients) in order to meet just 1 out of the 17 Stage 2 core measures under the Medicare incentive program. Not all patients would require a clinical summary after every office visit, especially non-Medicare patients, so the application of this Stage 2 measure to private payer patients burdens a physician's private payer practice with uncompensated services that do not necessarily improve quality of care.

Physicians are not expecting to apply and meet all of the meaningful use measures for their private payer business since the law and educational material from CMS and other stakeholders all specifically refer to Medicare and Medicaid patients and do not mention CMS' intention to expand the Medicare EHR incentive program requirements to a physician's entire patient population. Physicians have been told that they have to pick one EHR incentive program to participate in each year: Medicare or Medicaid, and cannot select both. Because they can only choose one program, physicians are assessing their Medicare and Medicaid patient volumes (and not factoring in their private payer patient volumes) to determine which program to participate in.

Further, CMS' intention to expand the meaningful use program to private payer patients conflicts with other Medicare incentive programs that prohibit such an expansion. For example, the Medicare e-prescribing incentive program requirements indicate that the incentives for e-prescribing are solely applicable to Medicare Part B services/patients and that e-prescribing for private payer patients does not count and is out of scope for the Medicare program. Expansion of the EHR program requirements to private payer patients is confusing to physicians and could deter physicians from taking part in the Medicare and Medicaid EHR incentive programs. **CMS' decision also raises serious privacy concerns.** A private payer patient (e.g., Blue Cross Blue Shield PPO patient) is not expecting that his/her confidential medical information can be disclosed to the federal government under the guise of the Medicare/Medicaid EHR incentive programs. According to our assessment of the Health Insurance Portability and Accountability Act (HIPAA) privacy rule, private payer patients would have to authorize the disclosure of their health information to CMS under the EHR incentive program since such a disclosure to CMS would not qualify under any of the HIPAA privacy rule exceptions (treatment, payment, or health care operations). Therefore, a private payer patient's formal consent would be required if CMS requires the inclusion of private payer identifiable patient data in Medicare meaningful use reporting.

While we expect that once physicians start using EHR systems, they would record information for their entire patient population, requiring physicians to apply Medicare and Medicaid meaningful use requirements that were specifically designed for the Medicare/Medicaid programs and patients to their non-Medicare/Medicaid patient practices is highly burdensome and of legal concern. Privacy rights must be upheld and the meaningful use program must neither undermine them nor place health care providers in an untenable position in this regard. **CMS should make it clear that physicians are NOT required to apply the Medicare/Medicaid meaningful use program requirements to their non-Medicare/Medicaid patient populations in order to be**

eligible for Medicare or Medicaid EHR incentives or in order to avoid Medicare financial penalties.

Recommendations on the Core Set of Measures Proposed for Stage 2

***EP Core Measure 1:** More than 60 percent of medication, laboratory, and radiology orders created by the EP during the EHR reporting period are recorded using CPOE.*

***Recommendation for Core Measure 1:** Remove 60 percent threshold requirement from Stage 2. Since laboratory and radiology orders are being added to Stage 2 requirements, EPs should only have to meet a 30 percent threshold and should have the flexibility to meet the measure by using CPOE for any of their orders (e.g., medication, laboratory, and radiology order) such that any combination of laboratory, radiology, and medication orders amounts to 30 percent.*

A November 2010 survey by the College of Healthcare Information Management Executives (CHIME) found that 15 percent of the 191 CHIME members surveyed believed that their hospitals would have everything in place during the first six months of fiscal year 2011 in order to successfully participate in the EHR meaningful use incentive program.⁵ The CHIME survey results also indicated that 62 percent of respondents anticipated challenges with the implementation of CPOE meaningful use measure.⁶ There are still challenges associated with CPOE use, even in hospitals. In addition, we lack survey data on physician use of CPOE in the ambulatory setting. 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). It is also important to keep in mind that meeting this measure as proposed for an entire calendar year would be extremely burdensome. More research is needed on CPOE use and challenges need to be identified and overcome prior to increasing the threshold amount for the CPOE use measure.

Given the continued documented challenges associated with the CPOE measure, we recommend that the threshold remain at 30 percent, and that physicians be provided with the option to use CPOE for any combination of laboratory, radiology, and medication orders. For example, a physician should be able to meet the CPOE measure with the 30 percent threshold on just medication orders, or could meet the CPOE measure with the 30 percent threshold on laboratory and radiology orders. This type of flexibility for Stage 2 is critical for physicians given that many of them still face a learning curve with the use of CPOE and would assist research efforts on CPOE in the ambulatory setting. Furthermore, it would allow added flexibility for specialists who may order more labs than x-rays. Challenges could then be identified based on physician participation rates and physician use of CPOE for one type of order vs. others.

***EP Core Measure 2:** More than 65 percent of all permissible prescriptions written by the EP are compared to at least one drug formulary and transmitted electronically using Certified EHR Technology.*

***Recommendation for Core Measure 2:** Threshold should only be increased to 50 percent and EPs should have the discretion (not be required) to review the drug formulary, if it is readily available. A broad exclusion category should also be established.*

We support the measure for generating and transmitting permissible prescriptions electronically, but recommend that the measure be modified so that EPs are only required to meet a 50 percent threshold requirement and have the discretion (not be required) to

⁵ College of Healthcare Information Management Executives survey on readiness for meaningful use, November 2010 (www.cio-chime.org/chime/press/surveys/pdf/chime_mu2_survey_report.pdf).

⁶ Id.

review the drug formulary, if it is readily available. Furthermore, there are still many prescriptions that cannot 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., mail orders). 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). Moreover, in many areas of the country there still exist “independent, single store” pharmacies not affiliated with large chains that lack e-prescribing capability. And, we continue to hear of situations where pharmacies that purport to accept electronic prescriptions are unable to do so or they lose the transmissions resulting in patient frustration and the requirement that physicians issue paper scripts.

Additionally, it is unfair to include this higher threshold for Stage 2 when several critical electronic prescribing standards have not been finalized (e.g., prior authorization, structured and codified SIG, clinical terminology). The Medicare Modernization Act of 2003 (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 should 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.

A case study reported in the January 2012 *Journal of the American Board of Family Medicine* indicated that the formulary and benefits information are complex and always changing which makes it difficult to rely on them for drug selection.⁷ Faced with this unreliability, many physicians reported that they have to rely on patients or pharmacists to notify them regarding medication costs or other health plan considerations in order to select an alternative medication.⁸ **Given challenges still experienced with formulary checks, we urge for the modification of the measure to not require formulary checks, unless the data quality problems associated with formulary and benefits information are fully resolved.**

CMS’ proposal to require that electronic prescriptions be sent to pharmacies outside the EP’s organization in order to count towards meeting this measure is unreasonable. **We recommend that electronic prescriptions sent to pharmacies within and outside the EP’s organization count towards meeting this measure.**

While we support exclusions for this measure including the one proposed by CMS that would allow EPs to be excluded from this measure if no pharmacies within 25 miles of an EP’s practice location at the start of his/her EHR reporting period accept electronic prescriptions, we believe a broader exclusion category should also be established. **We recommend that CMS establish an additional exclusion category that is broad enough to cover physicians who cannot meet the e-prescribing threshold requirement due to their individual hardship.** For example, physicians who treat a significant number of patients that reside in nursing homes may be unable to e-prescribe for these patients because the nursing home is responsible for the issuance of the prescriptions or the nursing home does not use a certified EHR. Another example concerns a

⁷ Jesse C. Crosson, PhD, Anthony J. Schueth, MS, Nicole Isaacson, PhD, MSS, and Douglas S. Bell, MD, PhD *Early Adopters of Electronic Prescribing Struggle to Make Meaningful Use of Formulary Checks and Medication History Documentation*. *Journal of the American Board of Family Medicine*. Available at: <http://www.jabfm.org/content/25/1/24.full.pdf+html>

⁸ Id.

physician who is unable to meet the threshold requirement due to issuing a large volume of mail-order prescriptions. We have heard from physicians that many mail-order pharmacies do not accept electronic prescriptions and still require that prescriptions be faxed in. The exclusion should also apply to physicians who mainly prescribe controlled substances. 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's (DEA) regulations for the e-prescribing of controlled substances. **Until the many challenges associated with e-prescribing referenced above are resolved, the threshold for the e-prescribing measure should only be increased to 50 percent and EPs should have the discretion (not be required) to review the drug formulary, if it is readily available in Stage 2. A broad exclusion category for physicians who cannot meet the e-prescribing threshold requirement due to their individual hardship should also be established.**

EP Core Measure 3: More than 80 percent of all unique patients seen by the EP during the EHR reporting period have demographics recorded as structured data.

Recommendation for Core Measure 3: EPs should only have to meet a 60 percent threshold for Stage 2.

We support this measure but believe that increasing the threshold amount from 50 percent (Stage 1 requirement) to 80 percent for Stage 2 is too steep of an increase. **We recommend that the threshold requirement be increased to 60 (not 80) percent for Stage 2.** A full evaluation of the Stage 1 measures would determine whether physicians are facing any issues with this particular measure. We support the inclusion of the recording of gender identity and/or sexual orientation, disability status, occupational demographics, etc., as optional information for physicians to record given that the capturing of this data is important for quality of care purposes for the appropriate specialties. Given the significant amount of information that physicians are being required to record under the meaningful use program, **we urge CMS to provide as much flexibility as possible so that physicians have the discretion to record information that they believe is relevant to the care that they provide to their patients.**

EP Core Measure 4: More than 80 percent of all unique patients seen by the EP during the EHR reporting period have blood pressure (for patients age 3 and over only) and height/length and weight (for all ages) recorded as structured data.

Recommendation for Core Measure 4: Remove this measure on vital signs from the core set and include it in the clinical quality measures section.

Recording vital signs belongs in the clinical quality measure set; not the core health IT measure set. The vital sign measure should be included in Table 8 within the clinical quality measure requirement for EPs to select from. We strongly support the use of health IT to improve public health goals, however, requiring physicians to attest to and/or report on metrics that are not clinically relevant to them and their patients, or to every encounter with a patient, does not help improve quality or practice workflow.

EP Core Measure 5: More than 80 percent of all unique patients 13 years old or older seen by the EP during the EHR reporting period have smoking status recorded as structured data.

Recommendation for Core Measure 5: Remove this measure on smoking status from the core set and include it in the clinical quality measures section.

Recording smoking status belongs in the clinical quality measure set; not the core health IT measure set. The smoking status measure should be included in Table 8 within the clinical

quality measure requirement for EPs to select from. We strongly support the use of health IT to improve public health goals, however, requiring physicians to attest to and/or report on metrics that are not clinically relevant to them and their patients, or to every encounter with a patient, does not help improve quality or practice workflow.

***EP Core Measure 6:** 1. Implement 5 clinical decision support interventions related to 5 or more clinical quality measures at a relevant point in patient care for the entire EHR reporting period, and 2. The EP has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period.*

***Recommendation for Core Measure 6:** EPs should only have to implement at a minimum 2 clinical decision support rules relevant to the clinical quality metrics the EP is responsible for. While we support the requirement to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period, there should be an exclusion category established for specialists who neither routinely prescribe medications nor actively participate in patient pharmacy management.*

We do not support CMS' proposed measure to require EPs to implement 5 clinical decision support rules relevant to the clinical quality metrics during Stage 2. The financial and staff resources associated with customizing these forms and tools should be taken into consideration before requiring a threshold of 5 clinical decision support rules be implemented in Stage 2. Appropriate rules must be derived from scientific evidence, much like measure development, and consensus. Once the clinical decision support rules are created, they then have to be incorporated into EHRs and this process, which takes time for vendors to implement and for physician offices to understand. According to a study published in the *Journal of the American Medical Informatics Association*, implementing clinical decision support systems is not always cost-effective.⁹ The study assesses the implementation of clinical decision support when treating patients with Type 2 diabetes.¹⁰ Researchers noted that the cost to design and implement the system was \$483,699.¹¹ CMS' proposal that requires physicians to implement a total of 5 clinical decision support interventions is highly burdensome given the financial and administrative costs associated with clinical decision support systems. CMS should thoroughly evaluate clinical decision support prior to making any major modifications to the Stage 1 requirements on clinical decision support. Moreover, the requirement to implement 5 clinical decision support 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 clinical decision support interventions for their particular patient populations given the specific type of care that they provide. **EPs should only have to attest to implementing no more than 2 clinical decision support rules during the reporting period for Stage 2.**

We do support the second part of the proposed measure that requires the EP to enable and implement the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period. Physicians should be provided with the flexibility to use their judgment regarding where to set the threshold setting. **We recommend, however, that an exclusion category be established for this second component for specialists who neither routinely prescribe nor actively participate in patient pharmacy management.**

⁹ http://jamia.bmj.com/content/early/2011/11/03/amiajnl-2011-000371.short?g=w_jamia Ahead Tab

¹⁰ Id.

¹¹ Id.

EP Core Measure 7: More than 55 percent of all clinical lab tests results ordered by the EP during the EHR reporting period whose results are either in a positive/negative or numerical format are incorporated in Certified EHR Technology as structured data.

Recommendation for Core Measure 7: Threshold should remain at 40 percent and this measure should continue to be a measure in the menu set for Stage 2.

While we support the incorporation of clinical lab-test results in EHRs and an exclusion category for this measure, we recommend that the threshold remain at 40 percent and this measure remain in the menu set for Stage 2. We believe that until such time that all laboratory service providers are obliged to follow an interface and transport standard for sending results to EHR systems, and EHR vendors are required as part of their certification criteria to be able to successfully accept such test results into the EHR system, this measure is too aggressive and burdensome to physicians due to the burden, required expertise, and cost of setting up functioning electronic laboratory interfaces. The manual data entry processes required to meet the measure would be far too costly, burdensome, and error-prone, with potential risks to patient safety and quality. Customized interfaces between an EHR and lab systems (which are predominantly hospital-based) do not exist on a widespread basis today, and even when they are technically feasible they are difficult and costly for physician practices to implement, test, and maintain. The incorporation of clinical lab results into EHRs 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. We have heard from physicians that this is an issue in their practices today; even if they have made a formal request for an interface, they languish for long and sometimes indefinite periods of time waiting for their request to be prioritized. There have also been reports from physicians on the difficulties in matching patients within the lab compendium resulting in problems with erroneous transactions and erroneous results reporting to incorrect patients.

Physicians and their staffs should not be expected to key in lab results simply because there is no ability for the lab to send these results directly to the EHR. It is incumbent upon the ONC to ensure the interoperability of EHR systems and advocate for the inclusion of expectations of laboratory service providers to follow a single standard that EHR vendors can adopt so that laboratory result interfaces can be easily created by EHR vendors and offered at little to no additional cost to physicians and other EPs who use their products.

We also heard from many physicians that they did not know how to account for laboratory tests that are ordered in a group or panel. These varying experiences prove that such a measure still belongs in the menu set. **This measure should, therefore, continue to be a measure in the menu set for Stage 2 and the threshold should remain at 40 percent.**

EP Core Measure 8: Generate at least one report listing patients of the EP with a specific condition.

Recommendation for Core Measure 8: We support this measure.

We support CMS' proposed measure for generating at least one report during Stage 2 listing patients with a specific condition. **Physicians should have the discretion to generate a report dependent upon clinical relevance to their patient population and at anytime during the EHR reporting period.** EHR products should include the functionality that enables physicians to easily do this.

EP Core Measure 9: More than 10 percent of all unique patients who have had an office visit with the EP within the 24 months prior to the beginning of the EHR reporting period were sent a reminder, per patient preference.

Recommendation for Core Measure 9: We support this measure but recommend that the measure not limit the sending of reminders to only those patients seen within 24 months prior to the beginning of the EHR reporting period. An additional exclusion category should be established for physicians for whom routine patient reminders would not be contextually relevant or appropriate.

We support CMS’ proposed measure for sending reminders to patients, but are concerned that the measure as written is inappropriately inflexible for many specialists. We support EPs utilizing this electronic capability as part of their daily work process, and believe that for Stage 2, 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. **The Stage 2 measure should be flexible enough to allow for reminders to be provided via phone calls, voice mail messages, emails, printed reminder notices 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 be sent. Physicians should have the flexibility to implement method(s) that work best for the physician practice and the patient.

We do not support the requirement that physicians only focus the sending of reminders to patients seen 24 months prior to the beginning of the EHR reporting period. This would be a challenging requirement for certain specialties and sub-specialists. Some services are one-time consultative visits so there is no need to send a reminder to the patient for a follow-up visit. We recommend that the measure include an exclusion for physicians who do not routinely send reminders to their patients given the type of care that they provide. 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. **This proposed measure is another example of where more flexibility is needed to accommodate varying physician practices. Physicians should have the flexibility to send reminders to patients, regardless of the date of their previous visit, and should be excluded from this measure if they do not typically send reminders.**

EP Core Measure 10: 1. More than 50 percent of all unique patients seen by the EP during the EHR reporting period are provided timely (within four business days after the information is available to the EP) online access to their health information subject to the EP's discretion to withhold certain information, and 2. More than 10 percent of all unique patients seen by the EP during the EHR reporting period (or their authorized representatives) view, download, or transmit to a third party their health information.

Recommendation for Core Measure 10: This measure should continue to be a measure in the menu set, and the threshold requirement should be increased to 20 (not 50) percent for Stage 2. The second component for patient review, download, or transmit, which unfairly predicates the physician’s success for meeting the measure on patient compliance, should be eliminated.

Although we support CMS’ proposed measure to provide patients with on-line access to their health information, we oppose the 50 percent threshold and the tight turn around time proposed by CMS that is inconsistent with the HIPAA rule, and we strongly oppose the second component of the measure that holds the physician accountable for patient compliance/non-compliance. We are concerned about the tight turn around time proposed in this measure because it is inconsistent with the HIPAA rule, which is more reasonable because it allows physicians a longer period of time to provide a patient access to their medical information.

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). Communication requires and benefits from a physician's knowledge of the patient, how the patient will accept the information, the impact of the information, etc. Physicians should have the discretion to make these determinations based on the physician-patient relationship. CMS should evaluate the reasonableness and burdensome nature of the four business day turn around time required by this measure, prior to moving this Stage 1 menu measure to the core set.

Implementing a patient portal to enable the secure, exchange of health information with patients is costly from both a financial and administrative standpoint. Obtaining a patient portal for an EHR system can be costly, and a physician practice would have to dedicate staff resources to managing the patient portal and patient communications. They must also ensure that the portal is compliant with HIPAA privacy and security requirements. It is important to keep in mind that for Stage 2, CMS is proposing that the reporting period be the entire calendar year. The sheer volume of patient information that has to be made available within four business days for the entire calendar year would be extraordinary for most practices and their staff to manage. This rigid measure does not take into account the realities of running a practice. Technological glitches, staffing shortages due to vacations, holidays, and other unforeseen circumstances occur throughout the calendar year and could cause a delay in providing the patient information within four business days. Such understandable delays could result in the physician not meeting this one measure, which would result in the physician not receiving incentives or ending up with a financial penalty. **Given the tight turn around time associated with this proposed measure, we recommend that this measure be retained in the menu set and that the threshold requirement be 20 (not 50) percent.**

We strongly oppose the second component of the proposed measure that holds physicians to a measure that is beyond their control. Physicians cannot force patients to view their health information on-line. 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, physicians should not bear the risk of being penalized for something that is an independent and potentially appropriate decision made by the patient. **We strongly recommend that any measures that require adherence from a party other than the physician, including this proposed measure, be removed from the meaningful use program.**

EP Core Measure 11: Clinical summaries provided to patients within 24 hours for more than 50 percent of office visits.

Recommendation for Core Measure 11: The turn around time for providing clinical summaries should remain at three business days and the threshold requirement should be 20 (not 50) percent. The measure should also be based on unique patients seen during the EHR reporting period, and not based on every office visit to minimize reporting burdens. In addition, a physician should have the flexibility to include only the information that the physician believes to be relevant for the summary.

Although we support in general CMS' proposed measure to provide patients with clinical summaries, we oppose the unreasonable tight turn around time, the prescriptive nature of the measure, and the 50 percent threshold requirement proposed by CMS. Physicians need

adequate time to complete a clinical summary after a patient visit. We do not want to turn patient visits into typing sessions where physicians are keying information into the EHR just so they can print a clinical summary after every visit rather than spending time communicating with their patients regarding their care. Physicians and patients are in the best position to determine information needed for the summary. 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 every visit the patient has with the physician during the EHR reporting period. If the EHR reporting period is the entire calendar year, it would be highly unlikely that physicians would be able to comply with a 24-hour turn around time for every patient for every visit. It would be especially challenging for certain specialists, including surgeons, to comply with the 24-hour turn around time given their unique work schedules. Care plans and complete dictation of the visit usually happen after the patient leaves and the chart note is completed. This rigid measure does not take into account the realities of running a practice. Solo and small practices do not have IT departments or IT experts readily available to them 24/7 to fix technological issues that may arise. Even in hospitals, IT support is markedly limited outside of the traditional 9-to-5 business week. Technological glitches, staffing shortages due to vacations, holidays, and other unforeseen circumstances occur throughout the calendar year and could cause a delay in providing clinical summaries within 24 hours. Such delays could result in the physician not meeting the measure, and not receiving incentives or ending up with a financial penalty.

We do support CMS' proposal to allow the EP to select any modality (e.g., online, CD, USB) as their electronic option, and CMS' proposal that the physician does not have to accommodate requests for different modalities. Physicians should also be allowed to provide printed summaries generated from their EHRs to their patients. This type of flexibility would accommodate Medicare patients who prefer printed summaries if they do not use or have access to computers.

We do not support CMS' proposal to prohibit EPs from charging the patient a fee for providing the clinical summary. The HIPAA rule specifically allows physicians the right to charge patients a reasonable fee for a copy of their health information or a summary or explanation of such information. It takes time and resources to put together a clinical summary and that is the reason why the HIPAA rule authorizes physicians to charge a reasonable fee for such time-consuming services. **We urge CMS to ensure that the Stage 2 rule is consistent with the HIPAA rule and allows physicians to charge patients a reasonable fee for providing them with a clinical summary based on their medical record.**

We are also concerned with CMS' proposal that every physician produce 20 items to be included in the clinical summary, including administrative related information that a physician may only retain in his/her practice management system, in order to meet this measure. Moreover, detailed information in 20 categories is more information than a patient routinely needs and risks confusing them with conflicting or excessive information. This proposal is too burdensome and overly prescriptive. Physicians are in the best position to determine what information needs to be included in the clinical summary for a particular visit. 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 the turn around time for providing clinical summaries remain at three business days, flexibility be provided on clinical summary content, and the threshold requirement should be 20 (not 50) percent.**

EP Core Measure 12: Patient-specific education resources identified by Certified EHR Technology are provided to patients for more than 10 percent of all office visits by the EP.

***Recommendation for Core Measure 12:** We support this measure but recommend that the measure not limit educational resources to those identified by Certified EHR Technology.*

We support this proposed measure on providing patients with patient-specific education resources, but recommend that the measure not limit educational resources to those identified by Certified EHR Technology. We agree with CMS' proposal that the resources or materials provided to patients do not have to be stored within or generated by the Certified EHR Technology. Physicians should also have the flexibility to provide these resources to patients in a useful format for their patients (e.g., electronic copy, printed copy, electronic link to source materials, through a patient portal or personal health record (PHR)). Requiring that the Certified EHR Technology specifically identify the educational resource can add value but the main issue is to ensure that patients receive relevant educational resources from whatever source is best suited to their needs, not just the resources that the Certified EHR is able to identify.

***EP Core Measure 13:** The EP performs medication reconciliation for more than 65 percent of transitions of care in which the patient is transitioned into the care of the EP.*

***Recommendation for Core Measure 13:** We support this measure.*

We support this measure on medication reconciliation. 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 and their patients. 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 accountable.

We agree that the measure on medication reconciliation should not dictate what information must be included in medication reconciliation or what actions must be taken with the information received. Information included and actions taken in the process of medication reconciliation is appropriately determined by the physician and patient, and other providers inside and outside the practice who may be involved in prescribing and management decisions but who are not necessarily available in real-time to finalize a decision as to whether a medication should be added, removed, or changed. We also support the proposed definition of a transition of care as the movement of a patient from one setting of care (e.g., a hospital, ambulatory primary care practice, ambulatory specialty care practice, long-term care, home health, rehabilitation facility) to another. In addition, we support that medication reconciliation encompasses the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency, and route, by comparing the medical record to an external list of medications obtained from a patient, hospital, or other provider. We also agree that the electronic exchange of information should not be a requirement for medication reconciliation and that while the objective is to conduct medication reconciliation at all relevant encounters, determining which encounters are relevant beyond transitions of care is too subjective to be included in the measure for Stage 2.

***EP Core Measure 14:** 1. The EP that transitions or refers their patient to another setting of care or provider of care provides a summary of care record for more than 65 percent of transitions of care and referrals and 2. The EP that transitions or refers their patient to another setting of care or provider of care electronically transmits a summary of care record using Certified EHR Technology to a recipient with no organizational affiliation and using a different Certified EHR Technology vendor than the sender for more than 10 percent of transitions of care and referrals.*

***Recommendation for Core Measure 14:** This measure should continue to be a measure in the menu set for Stage 2 and the threshold requirement should remain at 50 percent, and the second component of the measure that requires physicians to research what EHR technology other providers are using should be eliminated.*

We support providing a summary care record for transitions of care and referral but recommend that this measure continue to be listed in the menu set for Stage 2 and that the threshold requirement remain at 50 percent. We do not support, however, the second component of the measure which requires physicians to identify the EHR technology used by another physician or health care provider that they are transitioning or referring their patient to. This second component of this measure places a tremendous administrative burden on physicians to research what systems other providers are using and whether these systems are interoperable. Physicians also have no control over the systems that have been implemented in their particular market. Physicians' hands are further tied in markets where ONC's Regional Extension Centers (RECs) only recommend certain EHR products. ONC should ensure that EHR products that they certify are interoperable and enable the secure exchange of health information amongst health care providers. Physicians today are unable to exchange summary of care records with other EPs with different EHR technologies in different organizations, so this measure should not be a core measure in Stage 2. **Because of the continued challenges that physicians face with the lack of abundant health information exchanges, we recommend that this measure remain in the menu set and that the threshold requirement remain at 50 percent.** CMS should also allow more flexibility in meeting the measure for the electronic transmittal of a summary of care record by allowing the use of USB, CD-ROM, or other physical media or electronic fax. We also caution against requiring physicians to predicate meeting the measure on the use of certain transport standards over others. Physicians have no control over use of such standards within health information exchanges.

We would also like to point out our ongoing concerns with the discontinuation of CPT consultation codes in Medicare. CMS' final physician payment rule for 2010 asserted that there is no longer any significant difference between a consultation and a routine visit because consultants now can send referring physicians the medical record rather than a written report. Physicians have been forced to reduce services to Medicare patients and care coordination has suffered as a result of CMS' policy. These problems could be mitigated by revising CMS guidelines regarding prolonged visits and new patients and/or by creating some mechanism for reimbursing consultant physicians for a comprehensive report back to a referring physician.

***EP Core Measure 15:** Successful ongoing submission of electronic immunization data from Certified EHR Technology to an immunization registry or immunization information system for the entire EHR reporting period.*

***Recommendation for Core Measure 15:** This measure should continue to be a measure in the menu set for Stage 2 and should only require testing of the Certified EHR Technology's capacity to submit electronic data.*

While we generally support this measure for testing, we do not support moving this measure to the core set and requiring ongoing submissions as a condition to meet this measure. Interfaces with immunization registries and public health agencies do not readily exist. This measure also places a tremendous burden on physicians to research whether immunization registries or information systems in their jurisdiction are capable of accepting electronic immunization data. The burden should not be placed on individual physicians to figure out which immunization registries accept electronic immunization data.

CMS expects that CMS, the Centers for Disease Control and Prevention (CDC), and public health agencies would establish a process where they would be able to provide letters affirming that the EP was able to submit the relevant public health data to the public health agency. This affirmation letter could then be used by the EP for the Medicare and Medicaid meaningful use attestation systems, as well as in the event of any audit. Since there are no assurances that public health agencies would be able to provide affirming documentation to physicians and the interoperability capabilities of immunization registries or immunization information systems throughout the country have yet to be fully assessed and made known to physicians, **we recommend that this measure continue to be a measure in the menu set for Stage 2. In addition, physicians should only be required to test the submission function for Stage 2 in lieu of the proposed ongoing submission requirement.**

EP Core Measure 16: Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the encryption/security of data at rest in accordance with requirements under 45 CFR 164.312 (a)(2)(iv) and 45 CFR 164.306(d)(3), and implement security updates as necessary and correct identified security deficiencies as part of the provider's risk management process.

Recommendation for Core Measure 16: We support this measure.

We support this measure to conduct or review a security risk analysis in accordance with the HIPAA Security Rule. We continue to urge the Office for Civil Rights (OCR), ONC, and CMS to require vendors or make resources available to physicians to help them identify the specific technical capabilities that they would need to ensure patient information is appropriately protected and safeguarded. We also support CMS' proposal not to change the HIPAA Security Rule requirements, or require any more than would be required under the HIPAA Rule. In addition, we support CMS' proposal of emphasizing the importance of an EP or hospital including in its security risk analysis an assessment of the reasonable and appropriateness of encrypting electronic protected health information or using an equivalent method as a means of securing patient information. **We recommend that OCR develop a user friendly sample tool kit for physician practices that includes sample checklists, as well as other tools that physicians can implement in their practices in order to meet this measure.**

EP Core Measure 17: A secure message was sent using the electronic messaging function of Certified EHR Technology by more than 10 percent of unique patients seen during the EHR reporting period.

Recommendation for Core Measure 17: This measure should be placed in the menu set and be modified to read that the messaging is from the physician not the patients.

We do not support this measure as a core measure, and recommend that the measure be placed in the menu set for Stage 2, and that it be modified so that the messaging is from the physician, not the patient. First, because this is a proposed new measure, it is by definition untested and should therefore be placed in the menu set for Stage 2. We also have significant concerns with a proposed measure requiring physicians to email their patients. While advances in technology have affected the way that physicians and patients communicate, it is important to keep in mind that physicians and their patients are in the best position to determine appropriate communication vehicles. The meaningful use measures should not dictate to patients with what frequency they should communicate with their physicians using a specific medium or technology. We have serious concerns with this requirement, especially in the behavioral health setting. In addition, an unintended consequence of promoting that patients send electronic messages to their physicians is that patients who may find themselves in a life-threatening situation may turn to email as a means of communicating with their physician, rather than attempting to immediately

access their physician through the use of a telephone or pager or dialing 911. There are also legal concerns with this measure being in the core (required) set given that emails are discoverable in lawsuits, and so physicians may want to limit e-mail communications with their patients that are not as comprehensive as a face-to-face meeting, a phone conversation, or non-email written communication.

Further, we are concerned that the proposed measure is basing the physician's success for meeting the measure on patient compliance. Physicians cannot force a patient to use secure messaging. In addition, many certified EHR systems today enable a physician to send an unsecure e-mail message to the patient indicating to the patient that s/he should log into a secure portal to access their health information. A physician could not meet this measure as written using existing EHRs given that the original email to the patient is not through secure messaging. Another point of concern is that physicians who bill Medicare are not reimbursed under current payment policies for email communications with patients. **Physicians should not be forced to provide services that are not covered or non-billable under Medicare. Not only should this measure be placed in the menu set, but the measure should be modified and based on a physician's (not the patient's) issuance of electronic messaging.**

Recommendations on the Menu Set of Measures Proposed for Stage 2

EP Menu Measure 1: More than 40 percent of all scans and tests whose result is one or more images ordered by the EP during the EHR reporting period are accessible through Certified EHR Technology.

Recommendation for Menu Measure 1: We support this measure in the Stage 2 menu set but recommend that the threshold be decreased to 20 percent and that the numerator and denominator be further clarified.

While we support this measure for the Stage 2 menu set, we believe that high thresholds should be avoided for a new measure until the measure is fully evaluated. Given that this proposed measure is a new measure for Stage 2, we agree that this measure should be in the menu set of measures. We also believe that the threshold for this measure should be 20 percent. In addition, we do not support CMS' proposal that 10 percent of all scans and tests whose result is one or more images ordered by the EP during the EHR reporting period and accessible through Certified EHR Technology be exchanged with another provider of care. The images that are created may not be accessible due to the system of the EP or other health care provider who creates the images. It would be burdensome for the ordering EP to figure out which other providers have the ability to receive the images electronically since secure health information exchanges and interfaces do not readily exist.

There appears to be a conflict between the denominator (orders of imaging) and the language in the exclusion (no interpretations of imaging). Combined, these two elements of the measure assume that the EP who orders the imaging study is the same EP who is interpreting the images. While this may be true in some specialties (e.g., cardiology, dentistry, ophthalmology), in many clinical scenarios diagnostic radiologists interpret images that were ordered by a referring physician. This measure should be revised or clarified to either limit the application of the measure to ordering physicians (in which case a new exclusion is needed for those who do not order imaging but do interpret images) or to cover interpreting physicians (in which case the denominator needs to be changed to something other than orders).

We agree that there should be an exclusion for physicians who do not typically exchange imaging scans and test results as a normal part of their workflow. The quality of the images that are viewed, and/or distributed, should also be a complete set of diagnostic quality images. Until this

is possible, there will be a need to re-image, which is counter to public interest to reduce over-use of imaging. The diagnostic quality criterion should be consistent with AMA's recommendations on imaging safety and standards given that clinicians would be using images viewed in the EHR to make diagnostic decisions that affect patient management.

EP Menu Measure 2: More than 20 percent of all unique patients seen by the EP during the EHR reporting period have a structured data entry for one or more first-degree relatives.

Recommendation for Menu Measure 2: We support this measure in the Stage 2 menu set.

We agree that this measure should be placed in the Stage 2 menu set. We support the recording of patient family history. Not only is this information helpful from an effective screening and prevention standpoint, but is also important for genetics and personalized medicine. CMS proposes not to include the capability to exchange family health history electronically as part of the measure. We agree with CMS' proposal given that there is no sufficient structured data capture of family health history yet to support such an electronic exchange. A technological concern that should be addressed is that the Certified EHR Technology would have to be able to support the distinguishing between first degree and non-first degree relatives and the physician or staff would have to take the extra effort to designate the specific individual who had the history in ways that identify the person as a first degree relative or not. Then the EHR would have to correctly calculate the numerator as only looking for first degree relatives, not just any family history. **Given that this proposed measure is a new measure for Stage 2, we agree that this measure should be located in the menu set of measures.**

EP Menu Measure 3: Successful ongoing submission of electronic syndromic surveillance data from Certified EHR Technology to a public health agency for the entire EHR reporting period.

Recommendations for Menu Measure 3: We support this measure in the Stage 2 menu set, but this measure should only require testing of the Certified EHR Technology's capacity to submit electronic data.

While we generally support this measure in the Stage 2 menu set for testing, we do not support requiring ongoing submissions as a condition to meet this measure. Very few public health agencies are currently accepting syndromic surveillance data from physicians. Interfaces with registries and public health agencies are a work in progress. This measure also places a tremendous burden on physicians to research whether certain registries or public health agencies are capable of accepting electronic health data. The interoperability capabilities of public health agencies and registries throughout the country should be fully assessed and made known to physicians so that it is not a guessing game for individual physicians. We recommend that in order to meet this measure, physicians only be required to test the submission function in lieu of the proposed ongoing submission requirement. **Given the technological challenges associated with this measure, we agree that this measure should be located in the Stage 2 menu set.**

EP Menu Measure 4: Successful ongoing submission of cancer case information from Certified EHR Technology to a cancer registry for the entire EHR reporting period.

EP Menu Measure 5: Successful ongoing submission of specific case information from Certified EHR Technology to a specialized registry for the entire EHR reporting period.

Recommendations for Menu Measures 4 and 5: We support these measures in the menu set for Stage 2.

We support the use of registries. Many medical specialty societies have developed registries for clinical quality improvement purposes. Clinical registries are an important vehicle for monitoring

care patterns, evaluating health care effectiveness and safety, and improving clinical outcomes. **We recommend that the registries be defined in the broadest terms for these measures in the Stage 2 menu set.** For example, reporting cancer cases should not be limited to a state cancer registry. Physicians should have the flexibility of reporting to other registries to meet this measure, particularly if their state cannot receive electronic cancer case information. **Given that these proposed measures are new for Stage 2, we agree that these measures should be located in the menu set of measures.**

Proposed Clinical Quality Measures (CQMs) for EPs Beginning with CY 2014

CMS is proposing two reporting options that would begin in CY 2014 for Medicare and Medicaid EPs.

Option 1: CMS is proposing the following two alternatives, but intends to finalize only a single method:

- Option 1a: EPs would report 12 CQMs (from those listed in Table 8 of the proposed rule), including at least one measure from each of the six domains.
- Option 1b: EPs would report 11 "core" CQMs (listed in Table 6 of the proposed rule) plus one "menu" CQM (from Table 8).

Requiring EPs to report on 12 measures is too many and undermines the quality improvement intent of the program. Many of the measures are heavily weighed towards primary care and preventive medicine, which would make it difficult for some sub-specialties to find 12 CQMs to track. Many physicians will be forced to report zero values for many of the measures, which significantly undermines the utility of this process.

Further, we are concerned about both options 1a and 1b. Under option 1a, it would be difficult to identify CQMs that apply broadly across various medical specialties, and therefore some medical specialties would have trouble identifying 12 relevant measures on which to report. This is especially true with the requirement of identifying a measure from each of the six domains since some of these domains have a very limited number of measures.

We are also concerned that Option 1b would pose a significant challenge in identifying 11 "core CQMs" measures relevant to all EPs. This option would also undermine meaningful reporting since many EPs would be forced to report on measures that are not fully relevant, with a very small or nonexistent denominator value.

Because of these difficulties with the proposed options, we urge CMS to release data on Stage 1 reporting to determine which measures proved valuable and which ones were reported with a low number or zero in the denominator. We also urge CMS to consider a third option: EPs would report six clinically relevant CQMs, covering at least two domains. If an EP does not have clinically relevant measures, the EP's system must demonstrate zeros in the denominator for six measures covering at least two domains. This would be a much more feasible option that would help ensure EPs can identify measures relevant to their specialty.

Option 2: CMS is proposing Option 2, as an alternative to Options 1a or 1b, for Medicare EPs who participate in both the PQRS and the EHR meaningful use programs. Under Option 2, Medicare EPs, who submit and satisfactorily report PQRS CQMs under the PQRS EHR reporting option using Certified EHR Technology, would satisfy their CQM reporting requirement under the Medicare EHR Incentive Program. This option is intended to streamline quality reporting options for EPs.

We have long-advocated for alignment of the PQRS EHR reporting option with CQM reporting under the meaningful use program, and Option 2 is a positive step in that direction. Therefore, we support option 2. We encourage CMS, however, to double its efforts to ensure a sufficient number of approved CQMs and measures groups are available so that as many EPs as possible may take advantage of Option 2.

Certification Requirements for CQMs

CMS proposes that EHR Technology, certified by the ONC, will be required to report CQMs. Reporting methods may include attestation, reporting under the PQRS EHR reporting option, the group reporting options for EPs, the aggregate portal-based reporting methods, and the finalized reporting method for eligible hospitals and CAHs. In addition, for attestation and the aggregate portal-based reporting methods for EPs, eligible hospitals and CAHs, Certified EHR Technology must be certified to "incorporate and calculate" for each individual CQM that an EP, eligible hospital or CAH submits. EPs, eligible hospitals and CAHs must only submit CQMs that their Certified EHR Technology is explicitly certified to calculate in order to meet the meaningful use requirement for reporting CQMs.

We are concerned that the certification requirement may place the onus on EPs to determine whether a particular EHR Technology is certified. Particularly at the outset of the meaningful use program, it would be very difficult, burdensome, and expensive for EPs to determine independently what product is "certified," and for what measures it is certified. **Therefore, CMS should ensure that EPs are not penalized if it is later determined that a vendor has not met the certification requirement, especially if the EP is making a good faith effort to report CQMs under the meaningful use program. If an existing EHR is determined to be non-certified, this means an EP would be required to purchase additional certified modules, and their use would require onerous modifications to an EP's workflow. This burden and expense should not fall on EPs, and we urge CMS to ensure this does not occur. Further, we urge that to satisfy the capture and reporting of CQMs, EPs should only need their Certified EHR Technology to generate "zeros" in at least six measures covering 2 domains (consistent with our third option recommended above).** The CQMs a Certified EHR Technology can capture will vary by product, so it is critical that EHR vendors communicate clearly with end users about what measures its EHR products can capture. EPs should not be burdened with having to build out the quality logic to generate "zeros" for all of the CQMs their Certified EHR Technology may be capable of reporting on.

We also urge CMS to provide an exemption for EPs from the CQM requirements of the EHR meaningful use rule until measures have been tested and vendors have shown they have met the certification requirements for the specific EHR Technology being utilized by an EP.

Measure Specification

CMS discusses in the proposed rule that it may be necessary to remove a CQM from the EHR meaningful use program between rulemaking cycles. CMS states that when there is reason to believe the continued collection of a measure as it is currently specified raises potential patient safety concerns and/or is no longer scientifically valid, it would be appropriate for CMS to take immediate action to remove the measure from the EHR meaningful use program and not wait for the rulemaking cycle.

CMS also proposes that if a CQM undergoes a substantive change by the measure steward between rulemaking cycles such that the measure's intent has changed, CMS would expect to

remove the measure immediately from the EHR meaningful use program until the next rulemaking cycle when CMS could propose the revised measure for public comment. Under this policy, CMS would promptly remove such CQMs from the set of measures available for providers to report under the EHR meaningful use program, confirm the removal (or propose the revised measure) in the next EHR meaningful use program rulemaking cycle, and notify providers (EPs, eligible hospitals, and CAHs) and the public of CMS' decision to remove the measure(s) through the usual communication channels (memos, e-mail notification, website postings).

We support the above circumstances for removing CQMs between rulemaking cycles, but urge CMS to ensure that removal of a measure(s) does not penalize an EP that has been in the process of reporting on that measure. If a measure is removed from the program mid-cycle, the EP should simply have one (or more) less reportable measure(s) for that cycle, and should not be required to report on an additional measure(s) in place of the removed measure(s). Further, we urge CMS, upon removal of a measure, to inform the relevant measure developer of this decision, along with the rationale for its removal in order to provide measure developers an opportunity to revise the measure for future use.

Finally, regarding the removal of measures that undergo a “substantive change” by a measure developer such that the measure’s “intent” has changed, we urge CMS to clarify what types of changes will constitute a “substantive change,” resulting in a change of “intent” of the measure. **CMS should provide guidelines to better clarify “substantive change” resulting in a change in a measure’s “intent.”**

Finally, CMS proposes to post the complete measure specifications for the 2014 CQMs on the CMS website at or around the time of the final rule. We applaud this effort, and are pleased CMS plans to post these specifications well before the start of the 2014 program, giving EPs advance notice of these specifications and adequate lead time to prepare to report on the 2014 CQMs.

Testing Quality Measure Specifications

CMS states that the finalized list of measures that would apply for EPs beginning with CY 2014 will be published in the final rule. Further, because measure specifications may need to be updated more frequently than CMS expects the rulemaking cycle to allow for, CMS will provide updates to the specifications at least six months prior to the beginning of the calendar year for which the measures would be required, and CMS expects to update specifications annually. All clinical quality measure specification updates, including a schedule for updates to electronic specifications, would be posted on the EHR meaningful use program website.

We urge CMS to ensure that six months allows enough time for vendors and EPs to be informed of any changes in measures and measure specifications, with a timely opportunity to operationalize them to ensure accurate reporting and data capture for successful participation.

We are concerned CMS did not include in the proposed rule any discussion of testing the electronic specifications for any of the proposed measures. We urge CMS to ensure that specifications are tested prior to vendors imbedding them into their systems for use. Lack of this type of testing for Stage 1 CQMs caused significant difficulties for EPs trying to successfully attest.

If specifications are not tested, the information generated from using EHRs to report on CQMs could be inaccurate. Testing the EHR specifications for the measures first is critical to ensure accurate quality measure reporting and meaningful quality improvement. If CMS 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.

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.

As demonstrated through a project funded by the Agency for Health Care Research and Quality (AHRQ) entitled “Cardio HIT,” testing EHR specifications across varying practice sites using different health IT 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 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 CQMs on day one.

Further, because of the extensive and time consuming nature of this work, CMS should provide funding to ensure an appropriate testing process.

Time Periods for Reporting CQMs

CMS is not proposing any changes to the time periods for reporting CQMs. The EHR reporting period for CQMs under the EHR meaningful use program is the period during which data collection or measurement for CQMs occurs. The reporting period for EPs is consistent with the Stage 1 final rule, and will continue to track with the EHR reporting periods for the meaningful use criteria, as follows:

- EPs: January 1 through December 31 (calendar year).
- EPs (eligible hospitals and critical access hospitals (CAHs)) in their first year of meaningful use for Stage 1, the EHR reporting period would be any continuous 90-day period within the calendar year (CY) or federal fiscal year (FY), respectively.

To avoid a payment adjustment, Medicare EPs and eligible hospitals in their first year of demonstrating meaningful use in the year immediately preceding any payment adjustment year would have to ensure that the 90-day EHR reporting period ends at least three months before the end of the CY or FY, and that all submissions are completed by October 1 or July 1, respectively. If the EP is demonstrating meaningful use for the first time in CY 2014, for purposes of avoiding the payment adjustment in CY 2015, the EHR reporting period must end by September 30, 2014.

We support CMS’ proposal to allow EPs to report CQMs through attestation during Stage 1 of the meaningful use program. We also urge CMS to continue to allow EPs to report CQMs through attestation during Stage 2. This flexibility is critical due to the complexity of the program and measure specifications. Stage 2 measures include CQMs that reference specific months (e.g., influenza immunization) or a certain number of times per year that a medical service should be performed (NQF #0321-Peritoneal Dialysis Adequacy). There are also

two cataract measures (NQF #0564 and #0565) that look at either 30 or 90 days after cataract surgery for the numerator of the measure to be met. It likely would be very difficult to accurately capture the data, as well as calculate performance, on these types of CQMs during Stage 2. For example, if a patient has cataract surgery on November 15, there would not be sufficient time before the end of the reporting period (December 31) to capture the 90-day post surgery period. **Due to these difficulties, and without a comprehensive CMS survey of the ability of Certified EHR Technology to accurately capture CQM data, CMS should continue to allow CQM reporting through attestation during Stage 2.**

“Backdating” Performance Periods for Penalty Programs

We oppose the “backdating” of performance periods for any penalty program, including for CQM reporting under the EHR incentive program. Specifically, although the law requires penalties under Stage 2 of the Medicare/Medicaid meaningful use EHR program to begin in 2015, CMS is proposing that EPs who do not successfully meet meaningful use requirements in 2013 or by October 1, 2014 (for EPs who demonstrate meaningful use for the first time in CY 2014), will face a penalty starting on January 1, 2015. CMS is essentially pushing up deadlines for participation by up to two years, and this back-dating policy will subject a significant number of EPs to financial penalties and slow down the adoption and implementation rates of EHRs. **We, therefore, strongly oppose CMS’ backdating policy, and we urge CMS to establish a more reasonable timeline for the CQM performance year. The timing of the performance year should promote, not slow down, the adoption and implementation rates of EHRs.**

Further, different deadlines for submitting data under the meaningful use, PQRS, and value-based modifier programs, will be extremely burdensome and confusing for physicians. We urge CMS to align these data submission deadlines.

Additional CQMs

CMS is soliciting comment on a wide ranging list of 125 potential measures for EPs and 49 potential measures for eligible hospitals and CAHs, and expects to finalize only a subset of these proposed measures. These measures include those that address specialty areas that were not available in Stage 1. **We support CMS’ efforts to add more clinically relevant measures applicable across medical specialties since this will help ensure that reporting CQMs under the meaningful use program is not a “check-the-box” exercise, but rather is meaningful to improving the quality of patient care.**

Further, CMS plans to identify ways to minimize multiple reporting submission requirements and mechanisms across CMS reporting programs. For example, CMS is working toward allowing CQM data submitted via certified EHRs (by EPs and EHs/CAHs) to apply to other CMS quality reporting programs. **We applaud these alignment efforts.**

Proposed CQMs for EPs

CMS is required to give preference to CQMs endorsed by the National Quality Forum (NQF). CMS is proposing CQMs for EPs for 2013, 2014, and 2015 (and potentially subsequent years) that reflect this preference. However, CMS notes in the proposed rule that it is not required to select NQF-endorsed measures for the EHR Incentive Programs. Measures listed in the proposed rule that do not have an NQF identifying number are not NQF-endorsed, but are included in the proposed rule with the intent of eventually obtaining NQF endorsement.

We agree there should be a preference for NQF-endorsed measures. Yet, we appreciate and support CMS’ willingness to maintain flexibility by selecting measures that may not currently have NQF endorsement. The AMA-convened Physician Consortium for

Performance Improvement® (PCPI) has developed measures that are not yet NQF-endorsed simply because these have not been relevant to any previous NQF call for measures (e.g., wound care measures). Yet, we believe these types of measures should be eligible for selection by CMS as a CQM under Stage 2 of the meaningful use program.

Further, if CMS selects a non-NQF-endorsed CQM, and that measure later fails the NQF endorsement process, CMS should allow the measure to remain in the program until the next rulemaking cycle. Otherwise, an EP that is already reporting on the CQM will be unfairly penalized, especially since that EP will have already purchased Certified EHR Technology with functionality specifically for that CQM.

Further, CMS is proposing to increase the total number of CQMs for EPs in order to cover areas noted by commenters, such as behavioral health, dental care, long-term care, special needs populations, and care coordination. The new measures being proposed begin in CY 2014, and include new pediatric measures, an obstetric measure, behavioral/mental health measures, and measures related to HIV medical visits and antiretroviral therapy, as well as other measures that address National Quality Strategy goals. CMS plans to continue to develop or identify CQMs for dental/oral health care for future years. **We support CMS' efforts to increase the total number of measures available in the program and encourage CMS to continue working with measure stewards to ensure measures are electronically-specified as soon as possible.**

Proposed CQMs for EPs for CY 2013

CMS is proposing that for the EHR reporting periods in CY 2013, EPs must submit data for the CQMs that were finalized in the Stage 1 final rule for CYs 2011 and 2012. Updates to these CQMs' electronic specifications are expected to be posted on the EHR meaningful use program website at least 6 months prior to the start of CY 2013. **We commend CMS for the proposal to post updates to CQMs' electronic specifications at least 6 months prior to the start of CY 2013.**

Removal of Stage 1 Core CQM Measures in CY2014

Based in part on the feedback received throughout Stage 1, CMS is proposing to eliminate three CQMs beginning with CY 2014 for EPs at all Stages for the following reasons:

- NQF # 0013 – The measure steward did not submit this measure to the NQF for continued endorsement. CMS has included other measures that address high blood pressure and hypertension.
- NQF #0027 – CMS determined this measure is very similar to NQF #0028 a and b; therefore, to avoid duplication of measures, CMS is proposing to only retain NQF # 0028 a and b.
- NQF #0084 – The measure steward did not submit this measure to the NQF for continued endorsement. Additionally, CMS has decided to remove this measure because there are other FDA-approved anticoagulant therapies available in addition to Warfarin. CMS is proposing to replace this measure, pending availability of electronic specifications, with NQF #1525 – Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

We support removing Stage 1 measures #0027 and #0084, while retaining measure #0028. Regarding #0013, however, an update to this measure was submitted by the American College of Cardiology, American Hospital Association, and AMA-convened PCPI for consideration for continued NQF endorsement during the recent cardiovascular maintenance endorsement project.

Although the measure unfortunately was not recommended for endorsement during that project, we still support its consideration for inclusion in Stage 2 of the meaningful use program. The current portfolio of blood pressure measures included in Stage 1 of the meaningful use program fails to address two important and substantial groups of patients – patients with out-of-control and undiagnosed hypertension. A measure that identifies the proportion of patients with blood pressure in control and mandates a significant effort by clinicians to attempt to control patients with out-of-control hypertension through the use of antihypertensive medications would offer a better picture of the quality of care provided. This approach has not only been demonstrated to provide a more accurate reflection of the quality of care provided in the medical literature, but it is also more clinically credible and directly promotes the desired behaviors from clinicians managing the disease.

Capture of CQMs

We believe CQM exceptions provide actionable information for patient care and are important to quality measurement. Therefore, we encourage CMS to include the reporting of measure exceptions and mechanisms to do so, in addition to overall performance rates of CQMs, in the Stage 2 CQM certification criteria requirements.

We continue to explore an approach to quality measure exceptions that will ensure exceptions are collected as part of the clinical workflow and can be queried for automated quality reporting. In March 2012, the AMA-convened PCPI held a day-long multi-stakeholder meeting to evaluate options for specifying, documenting, and reporting quality measure exceptions within EHRs. CMS and the ONC participated in these discussions, along with other major stakeholders, including the NQF, EHR vendors, performance measure methodologists, and specialty society representatives. Participants in these discussions plan to formalize recommendations regarding the electronic capture of CQM exclusions later this year. In the meantime, exceptions will continue to have a place in quality measures developed by measure developers.

Definition of Group Practice

CMS is proposing, beginning with CY 2014, three group reporting options to allow EPs within a single group practice to report CQM data on a group level. One of these options allows groups to satisfy the PQRS Group Practice Reporting Option (GPRO) option using Certified EHR Technology. For purposes of the group reporting option under this EHR incentive program proposed rule, CMS defines a “group practice” as two or more EPs, each identified with a unique NPI associated with a group practice under one tax identification number (TIN). Yet, a group practice must involve 25 or more individual EPs under the PQRS GPRO option.

We appreciate and support CMS’ proposal to allow these group reporting options. We are concerned, however, that “group practice” is defined differently under the PQRS GPRO option. To avoid confusion, as well as further program alignment efforts, we urge CMS to align the PQRS and meaningful use definition of “group practice.” CMS should also continue to monitor the programs and adjust the threshold number of EPs necessary for a group practice in a manner that is reflective of group practice reporting patterns.

Changes to Stage 1 Requirements

CMS proposes several changes to existing Stage 1 meaningful use requirements. Some of these changes would be optional for use by physicians in Stage 1, beginning in 2013, but would be required for use in Stage 2, beginning in 2014. Other changes would not take effect until Stage 2. The proposed changes include:

- Changes to the CPOE measure by replacing the number of unique patients with the number of orders for medications, for the denominator (optional for Stage 1, required for Stage 2);
- Changes to the exclusions and age limitations for vital signs (optional for Stage 1, required for Stage 2);
- Elimination of the “exchange of key clinical information” core measure from Stage 1 and replaced with a “transitions of care” core measure that requires electronic exchange of summary of care documents in Stage 2 (effective for Stage 2);
- Replacing “provide patients with an electronic copy of their health information” measure with a “view online, download and transmit” core measure (effective for Stage 2); and
- Expanding the definition of what constitutes a Medicaid patient encounter to include encounters for individuals enrolled in a Medicaid program, including Title XXI-funded Medicaid expansion encounters (but not separate CHIP programs). In addition, CMS proposes flexibility in the look-back period for Medicaid patient volume to be over the 12 months preceding attestation, and not tied to the prior calendar year.

We support CMS’ above-referenced proposed change to the existing Stage 1 CPOE meaningful use requirement. Education and outreach is critical so that physicians are well-versed on changes to the Stage 1 requirements and their effective dates. We also refer CMS to our above stated comments on and recommendations for CPOE, recording of vital signs, summary of care, and providing patients with electronic access to information measures. In addition, **we urge CMS to make the proposed changes to the Medicaid patient encounter definition effective immediately upon the issuance of the final rule so that more physicians and other EPs can take advantage of the Medicaid EHR incentives.**

Meaningful Use Penalty Phase and Exemptions

The Medicare Meaningful Use EHR program has a penalty phase that starts in 2015. CMS proposes that any Medicare physician who successfully demonstrates meaningful use in 2013 would be exempt from a penalty in 2015. Also, any Medicare physician that first demonstrates meaningful use in 2014 would be able to avoid the penalty in 2015 if s/he meets the attestation requirement by October 1, 2014. In addition, meaningful use attestations to State Medicaid Agencies by physicians who are eligible for either Medicare or Medicaid EHR incentives, but opted for Medicaid incentives, would be accepted to avoid the Medicare penalty. However, the receipt of Medicaid EHR incentive payments for the initial Medicaid payment year would not be considered as satisfying the meaningful use criteria. Under the first year of the Medicaid EHR incentive program, an eligible physician only has to adopt, implement, or upgrade a certified EHR. **Therefore, physicians eligible for Medicare incentives in 2014, but who chose to participate in the Medicaid EHR incentive program and who have only adopted, implemented, or upgraded a certified EHR without meeting meaningful use measures, would be subject to a Medicare EHR penalty.**

We strongly oppose the back-dating of the meaningful use penalty program, and urge CMS to not back-date the meaningful use penalty program and any other quality or health IT penalty program, including e-prescribing and PQRS. If Congress intended that these penalty programs be back-dated, the legislation would have stated so. CMS is essentially pushing up deadlines for participation by a full year or more due largely to its own data processing limitations. We are sympathetic to the problem, but do not agree that there is no other solution. **We strongly urge CMS to allow physicians to successfully meet Stage 2 meaningful use measures for 90 consecutive days during the first six months of 2015 in order to avoid the 2015 penalty. We further recommend that this same 90-day policy to avoid penalties be**

extended to penalty years 2016 and 2017, and that the penalty program requirements be revisited in future rulemaking to ensure that the penalty program is fair and reasonable.

ARRA also authorizes the Secretary of HHS to establish exemption categories to exempt physicians and other EPs from penalties associated with the meaningful use program.

CMS proposes the following penalty exemption categories:

- Exemption for hospital-based physicians and other hospital-based EPs¹²;
- Exemption due to lack of availability of internet access or barriers to obtaining IT infrastructure;
- Exemption for newly practicing physicians; and
- Exemption for unforeseen circumstances such as natural disasters that would be handled on a case-by-case basis.

We support the above-referenced exemption categories. In addition, CMS proposes an exemption category for physicians who face the following three barriers all at once: lack of face-to-face or telemedicine interaction with patients; lack of need for follow up care for patients; and lack of control over the availability of Certified EHR Technology. We agree that physicians would face significant hardships if they fell into all of these three categories at once. However, we believe that each one of these categories on its own could pose a significant hardship for a physician. For example, some physicians who provide services (e.g., open access colonoscopies) in ambulatory surgical centers may lack face-to-face interaction with patients. These physicians would have a difficult time meeting many of the Stage 2 measures because the Stage 2 measures as a whole are not relevant to their routine scope of practice and the type of service that they provide to patients and would therefore be extremely burdensome or impossible to meet. **We strongly recommend that physicians who fall into one or more of these three categories be able to qualify for an exemption from the meaningful use penalties.**

While we support the above-mentioned penalty exemption categories proposed by CMS, additional exemption categories are necessary. The law authorizes the Secretary of HHS to establish as many exemption categories as needed in order to make the program fair and to protect physicians facing hardships from financial penalties. **We strongly recommend that the exemptions apply for 5 calendar years, which the statute authorizes, to minimize filing burdens and to allow time for CMS to reassess program requirements and timelines. If the participation rates are low and/or too many physicians are applying for exemptions, then significant changes need to be made to the meaningful use program requirements in the penalty phase, and exemption categories may need to be revised and additional ones developed.**

We also recommend that the following additional exemption categories be established:

- Exemption for a physician who successfully participates in the meaningful use program from PQRS penalties. The ACA calls for the integration of the clinical quality measure reporting under the PQRS and meaningful use programs. This exemption category would be an opportunity to synchronize the meaningful use and PQRS programs by

¹² Hospital-based is defined as an eligible physician or other EP who furnishes ninety percent or more of his/her covered professional services in a hospital setting in the year preceding the payment year, or in the two years before the payment penalty year (e.g., 2013). Hospital setting means sites of service codes used for inpatient hospital or emergency room setting.

exempting physicians from a penalty under the PQRS program if they successfully participate in the meaningful use program by reporting on CQMs in accordance with the meaningful use program requirements;

- Exemption for a physician who successfully met Stage 1 requirements in 2013, 2014, or in 2015. Physicians should not be penalized if they are making a good faith effort to meet meaningful use measures;
- Exemption for a physician who is using his/her certified EHR product(s), but is only able to meet 50 percent of the meaningful use measures because collecting data, electronically exchanging information, and/or running reports has proven to be difficult due to EHR product design and/or malfunctions, lack of vendor support, etc.;
- Exemption for a physician whose EHR loses its certification status or is not upgraded to meet certification criteria;
- A broad exemption category for physicians so that physicians are able to apply for a hardship exemption based on their individual circumstances. For example, physicians who are not hospital-based but believe that they would not be able to meet most of the measures because they do not routinely see patients or are usually on the receiving end of orders or for those physicians for whom house calls are a component of their practice should be able to apply for an exemption under this broad category. Another example applicable under the broad exemption category would be for solo or small physician practices that attempted to meet Stage 1 or Stage 2 meaningful use measures, but were not able to meet all of the meaningful use measures because they faced challenges (e.g., staffing issues, reimbursement delays or administrative burdens caused by HIPAA transition(s)); and
- Exemption for physicians who are currently eligible for Social Security benefits or will be eligible for Social Security benefits by 2014. It would be economically burdensome for physicians who intend to retire in the next several years to purchase, install, and meaningfully use an EHR. We are also concerned that many of these physicians may decide to close their Medicare fee-for-service panels or opt out of Medicare to avoid penalties during the end stage of their clinical careers, which would adversely affect access to care for our nation's elderly and disabled. Physicians who are currently eligible for Social Security retirement benefits or will be eligible for Social Security retirement benefits by 2014 should have the opportunity to apply for an exemption from the meaningful use program penalties.

Medicare E-prescribing Penalty Program Issues

We recognize that Congress created these programs in various pieces of legislation without adequate consideration of how these policies intersect. In addition, CMS does not have sufficient resources to seamlessly implement these programs. In accordance with President Obama's January 18, 2011, Executive Order calling on federal agencies to reassess and streamline regulations, CMS has an opportunity to minimize regulatory burdens on physicians by synchronizing the e-prescribing, PQRS, and meaningful use programs. Physicians are being required to meet separate requirements under these three overlapping health IT programs and have been and will be unfairly penalized if they decide to participate in one program over the other. These burdens are coming at the same time that physicians are trying to undertake meaningful payment and delivery reforms. We, therefore, urge CMS to consider the connection and impact of all these programs on physicians.

Further, the back-dating of the reporting requirements under all of these three programs not only runs counter to the language in statute that does not call for back-dating of reporting periods, but creates an additional obstacle course that physicians have to navigate through in order to avoid

financial penalties. CMS has essentially pushed up deadlines for participation by a full year or more due to its own administrative issues, and as a result this back-dating policy will unfairly subject a significant number of physicians to financial penalties and slow down the adoption and implementation rates of EHRs. **The physician community strongly disagrees with CMS' interpretation of these penalty timelines.**

We are adamantly opposed CMS' back-dating policy on all of the quality and health IT penalty programs. Rather than continuing to back-date the multiple penalty programs soon to hit physicians, we urge CMS to: establish a new reporting period for e-prescribing in 2012 and apply the 2012 e-prescribing penalty in 2013; revise implementation of the base initial performance year for the value-based modifier, the 2013 and 2014 e-prescribing penalties, the 2015 PQRS penalty, and penalties for the meaningful use EHR program. Relief from this back-dating policy will also prevent the ludicrous scenario in which physicians could receive an incentive payment and a penalty in the same year for the same program. Clearly, such a situation undermines any incentive for greater reporting or use of health IT.

Every health IT program has its own unique requirements, and some of these requirements have been changed (e.g., G-code for e-prescribing) so it is highly burdensome for physicians to have to keep up with all of the varying health IT program requirements and subsequent changes to these programs. Physicians should not be penalized if they decide to participate in one health IT program over the others or if they made good faith efforts to comply with program requirements. Therefore, we urge CMS to establish exemption categories under the Medicare e-prescribing and meaningful use programs to protect physicians facing these types of hardships. Both the e-prescribing and meaningful use programs provide the Secretary of HHS with discretion to develop as many exemption categories as needed to protect physicians from penalties. **CMS should add more exemption categories to the Medicare e-prescribing and meaningful use programs—a solution to better synchronize these overlapping health IT programs and protect physicians who face hardship from penalties.**

We urge CMS to establish the following exemption categories under the Medicare E-prescribing Penalty Program:

- Exemption category under the 2012, 2013, and 2014 Medicare e-prescribing penalty program for a physician who is registered to participate in the meaningful use EHR incentive program in 2012, 2013, or 2014, and is using certified EHR technology to e-prescribe;
- Exemption category under the 2012, 2013, and 2014 Medicare e-prescribing penalty program for physicians who did e-prescribe in accordance with the program requirements but uncover that their claim submissions were missing the G8553 code due to administrative or system errors (e.g., clearinghouse stripped the G-code from the claim form);
- Exemption category under the 2012, 2013, and 2014 Medicare e-prescribing penalty program for physicians who mistakenly included a 2009 e-prescribing G code rather than the G8553 code on their Medicare Part B claims; and
- Exemption category under the 2012, 2013, and 2014 Medicare e-prescribing penalty program for physicians who are unable to electronically prescribe due to local, State or Federal law or regulation, (e.g., physicians who mainly prescribe narcotics should be exempt from e-prescribing penalties).

CMS should allow physicians the opportunity to apply on-line for exemption requests. If a physician is already registered for the meaningful use program, s/he should only have to apply once for an exemption. The exemption should apply to the physician through 2014, the sunset year of the Medicare e-prescribing penalty program. Given the high volume of physicians who believed that they received a 2012 penalty in error, CMS agreed to open up their phone lines to take calls from physicians in order to address their concerns with the e-prescribing penalty program, which the physician community strongly supports. CMS should provide feedback reports for e-prescribers so physicians can assess their prospects for incentives or penalties. **We also urge CMS to establish an appeals process for the duration of the e-prescribing penalty program for physicians who believe that the Medicare e-prescribing penalty was applied to them in error.**

Due to the number of health IT programs currently underway and the hurdles faced with the implementation of the 2012 Medicare e-prescribing penalty program, physicians need more time to e-prescribe and report on their e-prescribing activity and to apply for an exemption if they are facing hardships in order to avoid penalties. **Along with establishing the above-mentioned exemption categories, we strongly urge CMS to extend the deadline from the current June 30, 2012, deadline to September 30, 2012 for applying for an e-prescribing exemption or for meeting the 2013 Medicare e-prescribing requirements (issuance of and reporting on 10 electronic scripts) in order to avoid the 2013 Medicare e-prescribing penalty.**

Exemption from any Reporting Program Penalty for Physicians Close to Retirement

If a physician is currently eligible for Social Security retirement benefits or will be eligible for these benefits by 2014, the physician should be exempt from the e-prescribing, PQRS, and meaningful use EHR penalty programs. It would be economically burdensome for physicians who intend to retire in the next several years to install and use an e-prescribing or EHR system. It would also be wasteful to our health care system overall for these physicians to make a long-term investment in purchasing these costly systems for extremely short-term use. We are concerned that many of these physicians may decide to close their Medicare fee-for-service panels or opt out of Medicare to avoid penalties during the end stage of their clinical careers, which would adversely affect access to care for our nation's elderly and disabled. These physicians are also concerned about privacy and security risks with collecting patient information electronically and the high administrative and financial burdens of properly securing or disposing of their mass collection of electronic patient data when they retire or close their practices. Recent HIPAA privacy and security fines against HIPAA covered entities have been in the range of hundreds of thousands or even millions of dollars. From a privacy and security standpoint, it could be financially and legally risky for physicians who plan on retiring in the next five years to implement health IT, when unintended breaches could cost them millions of dollars in fines.

Recoupment Process

We strongly oppose CMS' policy to require physicians to re-calculate beneficiary co-payments or deductibles if the physician is subject to a health IT financial penalty. It would be excessively burdensome or impossible for physicians to have to manually calculate adjustments for every Medicare patient's co-payment or deductible. Many times, physicians are not even aware of the amount of the co-payment or deductible owed by the patient until the physician receives the Medicare remittance advice. We recommend that CMS should estimate or calculate the total amount the physician owes Medicare and take a lump sum payment for it or a set amount per month rather than reducing the entire fee schedule.

Appeals Process

CMS proposes to establish an appeals process for Stages 1 and 2 that permits the filing of three types of appeals: (1) eligibility appeals; (2) meaningful use appeals; and (3) incentive payment appeals. There would be two levels in the appeals process: an informal review and a final reconsideration. The administrative review and appeal process would have to be exhausted prior to seeking review in federal court.

CMS proposes the following filing deadlines for each appeal:

- An eligibility appeal must be filed no later than 30 days after the 2-month period following the payment year;
- A meaningful use appeal must be filed no later than 30 days from the date of the demand letter or other finding that could result in the recoupment of an EHR incentive payment; and
- An incentive payment appeal must be filed no later than 60 days from the date the incentive payment was issued or 60 days from any federal determination that the incentive payment calculation was incorrect (including determinations that payments were duplicative).

We strongly support the establishment of an appeals process for the meaningful use program. In addition, we support the three types of appeals proposed. We recommend that a fourth type of appeal be established for exemptions and penalties phase of the program. We have learned significant lessons from the implementation of the 2012 Medicare e-prescribing penalty program, which resulted in a significant number of complaints from physician practices. Physicians who in good faith applied for exemptions ended up facing penalties through no fault of their own. For example, many physicians who filed for an exemption from the 2012 e-prescribing penalty provided their group rather than their individual National Provider Identifier (NPI) number on their exemption form. Unfortunately, CMS' exemption request page did not specify which NPI number was required. Because CMS needed the individual NPI numbers to run reports on their end in order to process exemption requests, physicians who reported their group NPI number ended up with their exemption request being denied and a 2012 e-prescribing penalty. CMS, the AMA, and other physician organizations had to field thousands of emails and phone calls from physicians outraged that they received a penalty despite the fact that they did the right thing and filed for an exemption on-time. CMS had to spend significant resources re-processing these and other erroneous denials and claims payment reductions. **Given our recent experience with the Medicare e-prescribing penalty program and the technical and administrative hurdles associated with implementing penalty programs, we strongly urge CMS to establish an appeals category for issues relevant to the exemption request process and penalty phase.**

We urge CMS to harmonize the proposed reconsideration and appeals process with the existing original Medicare fee-for-service reimbursement appeals process. While we strongly support the proposed two-step administrative appeals process and do not want the process expanded to three or four levels of review before a physician is able to seek federal court review (as is the case with the current reimbursement appeals process), we urge CMS to adopt a process that is consistent with Medicare's fee-for-service appeals process. **We urge CMS to provide physicians with 180 days to file an appeal after receiving actual notice of determination(s) that are subject to appeal at all levels of appeal.** It takes a significant amount of time and resources to collect information necessary to file for an appeal. Physicians should be provided with ample time to file an appeal based on issues including, eligibility, meaningful use requirements, incentive payments, or exemptions and penalties. In addition, we

urge CMS to permit physicians an opportunity to augment the evidentiary record. Often times, physicians are not represented by legal counsel (as it would be cost prohibitive) and may not understand what information should be submitted to document a claim or may not have it readily available. Medicare appeals have historically been very difficult for physician practices to navigate. The uptick in audits has exacerbated the frustration with the arcane and confusing rules that already exist. We are concerned that creating an appeals process in the Medicare program with extremely different deadlines and requirements will increase the administrative burden on physicians as well as the agency. We urge CMS to take this approach in the interest of administrative simplification and in order to reduce the regulatory burden and costs for physicians.

CMS also proposes to allow physicians up to seven calendar days to comply with the request for supporting documentation. Missing this seven day deadline would result in the dismissal of the appeal, except in extenuating circumstances. We do not support the unreasonable short turn around time proposed by CMS. **We urge CMS to allow physicians at the minimum 30 days to comply with the request for supporting documentation.**

In addition, CMS proposes that physicians dissatisfied with an informal review decision would be able to file a request for reconsideration of issues denied in the informal review decision. All comments and documentation supporting the health care provider's position would be required to be submitted within 15 days from the date of the informal review decision. **Again, we urge CMS to provide physicians with ample time to file for a reconsideration. CMS should at the minimum, provide physicians with 180 days from the date of the informal review decision to file for a reconsideration. We do support CMS' proposal to allow physicians a one-time extension, but we recommend that physicians be provided with at the minimum of 30 additional days with no strings attached.**

EHR Reporting Period for Incentives Revised

CMS proposes to revise the EHR reporting period definition so that the EHR reporting period is 90 consecutive days within a calendar year for physicians who are demonstrating meaningful use for the first time regardless of the payment year. **While we support this change, we also urge CMS to allow physicians the option to follow the 90 consecutive day reporting period at the beginning of each Stage (Stages 1, 2, and 3).** The Stage 2 requirements are more burdensome to meet than the Stage 1 requirements. Physicians, especially solo and smaller practices, need time to become well-versed in the new requirements so they may need to perform a dry-run prior to fully implementing all new measures for Stage 2. **Allowing physicians the option during their first year in Stage 2 to meet Stage 2 measures for 90 consecutive days would make the program more reasonable and achievable.**

Meaningful EHR User Definition Revised

CMS proposes revising a portion of the meaningful EHR user definition to read: “(3) to be considered a meaningful EHR user, at least 50 percent of an eligible professional’s (EP) patient encounters during an EHR reporting period for a payment year (or during an applicable EHR reporting period for a payment adjustment year) must occur at a practice/location or practices/locations equipped with Certified EHR Technology.” For example, if the physician practices at a federally qualified health center (FQHC) plus two different individual practice locations, CMS proposes to include all three of these locations, and the Certified EHR Technology would have to be available at one location or a combination of locations where the physician has 50 percent or more of his/her patient encounters. **We support CMS’ proposal that clarifies the amount of patient encounters required at multiple locations for meaningful users.**

We do not support however, CMS’ proposal to not allow physicians beginning in 2013, to create a record of the patient encounter without using Certified EHR Technology at a practice/location and then later inputting that information into Certified EHR Technology that exists at a different practice/location. Physicians should have this flexibility, especially if they work in multiple sites and some of those sites lack Certified EHR Technology to input data into a certified EHR at a different practice/location.

Unique Patient Definition for Stage 2

CMS proposes that the term “unique patient” for denominator purposes means that if a patient is seen more than once during the EHR reporting period, the patient only counts once in the denominator. A patient is seen by the EP when the EP has an actual physical encounter with the patient in which they render any service to the patient. A patient seen through telemedicine would also still count as a patient “seen by the EP.” In cases where the EP and the patient do not have an actual physical or telemedicine encounter, but the EP renders a minimal consultative service for the patient (like reading an EKG), the EP may choose whether to include the patient in the denominator as “seen by the EP” provided the choice is consistent for the entire EHR reporting period and for all relevant meaningful use measures. For example, a cardiologist may choose to exclude patients for whom they provide a one-time reading of an EKG sent to them from another provider, but include more involved consultative services as long as the policy is consistent for the entire EHR reporting period and for all meaningful use measures that include patients “seen by the EP.” EPs who never have a physical or telemedicine interaction with patients must adopt a policy that classifies at least some of the services they render for patients as “seen by the EP,” and this policy must be consistent for the entire EHR reporting period and across meaningful use measures that involve patients “seen by the EP”—otherwise, these EPs would not be able to satisfy meaningful use, as they would have denominators of zero for some measures. In cases where the patient is seen by a member of the EP’s clinical staff the EP can include or not include those patients in their denominator at their discretion as long as the decision applies universally to all patients for the entire EHR reporting period and the EP is consistent across meaningful use measures. In cases where a member of the EP’s clinical staff is eligible for the Medicaid EHR incentive in their own right (for example, nurse practitioners (NPs) and certain physician assistants (PA)), patients seen by NPs or PAs under the EP’s supervision can be counted by both the NP or PA and the supervising EP as long as the policy is consistent for the entire EHR reporting period. **We generally support CMS’ definition for a unique patient for denominator purposes and the flexibility that it would provide to practices to determine which patients would be applicable for the denominator. However, as we previously discussed, appropriate exclusions need to be available for physicians who do not routinely have physical or telemedicine interactions with patients.**

Group Reporting Option

We support CMS’ proposal on a reporting option that allows groups an additional reporting option in which groups report for their EPs as a whole rather than broken out by individual EP. Please also refer to our recommendation for CQM reporting with regard to aligning the definition of group practice across programs.

Waiver of Sunset Date for Exception and Safe Harbor

We urge CMS and the Office of Inspector General (OIG) to waive the current sunset date for the existing EHR exception to the Physician’s Self-Referral Law (Stark) and the Anti-Kickback Statute safe harbor. An important part of EHR adoption is “knowing what the rules are” in advance because EHR adoption is time consuming and expensive. Physicians who seek to adopt EHRs and utilize them in their practices should be assured that their systems will not run

afoul of the program integrity laws when those protections expire after 2013. By making the exception and safe harbor protections permanent, CMS and OIG would foster continued EHR adoption and use.

Medicaid EHR Incentive Program

We agree with CMS' proposal to offer States flexibility with the public health measures and the measure to generate lists of specific conditions to use for quality improvement, reduction of disparities, research or outreach, in Stage 2.

Educational Resources

CMS has prepared a considerable amount of information on its website on the meaningful use EHR incentive program (<https://www.cms.gov/EHRIncentivePrograms/>). Upon issuance of the final rule on Stage 2 measures, we recommend that CMS also post Stage 2 meaningful use specification sheets for EPs, similar to the ones already developed for Stage 1 measures. These specification sheets are user friendly and provide clear direction to the EPs on each measure and define key terms, the numerator, denominator, and exclusions, and provide additional helpful information, including links to relevant FAQs on CMS' website.

We are committed to working with CMS and ONC to ensure that the final Stage 2 regulations truly foster EHR adoption and 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, the American Medical Association's Assistant Director, Division of Federal Affairs, at 202-789-7414 or mari.savickis@ama-assn.org.

Sincerely,

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